EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-41

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Clean Water Act/Pebble Deposit
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	E Risk Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/12/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee:	LOE:
Cumulative Approved:		Cost/Fee:	LOE:

Work Assignment Manager Name: Christopher Hunter (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1454 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-41

TITLE: Technical Support for Response to "*Proposed Determination Pursuant to Section 404(c) of the Clean Water Act for Pebble Deposit Area, Southwest Alaska*"

Specify Section & Paragraph SOW: E Risk Assessment Support

PERIOD OF PERFORMANCE: *CO award through 10/31/2015*

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) in responding to public comments and technical data received on the Proposed Determination under Section 404c of the Clean Water Act for the Pebble Deposit Area of Alaska.

II. BACKGROUND

EPA Region 10 has requested public comment on a Clean Water Act (CWA) Section 404(c) Proposed Determination (PD) to restrict the use of certain waters in the Bristol Bay watershed for disposal of dredged or fill material associated with mining the Pebble deposit, a large ore body in southwest Alaska. EPA is taking this step because of the high ecological and economic value of the Bristol Bay watershed and the assessed unacceptable environmental effects that could result from such mining.

Section 404(c) of the CWA authorizes EPA to prohibit, restrict, or deny the use of any defined area in waters of the United States for specification as a disposal site whenever it determines, after notice and opportunity for public hearing, that the discharge of dredged or fill material into the area will have an unacceptable adverse effect on fishery areas (including spawning and breeding areas). Given the proposals made by NDM to develop 2.0- and 6.5-billion-ton mines at the Pebble deposit (Ghaffari et al. 2011, SEC 2011) and EPA's evaluation of a 0.25-billion-ton mine (EPA 2014), the Regional Administrator has reason to believe that mining of the Pebble deposit at any of these sizes, even the smallest, could result in significant and unacceptable adverse effects on ecologically important streams, wetlands, lakes, and ponds and the fishery areas they support.

To protect important fishery areas in the Bristol Bay watershed from unacceptable adverse effects, EPA Region 10 has proposed a set of restrictions related to losses of streams, wetlands, lakes, and ponds and alterations of streamflow, which are put forth in the document *Proposed Determination of the U.S. Environmental Protection Agency Region 10 Pursuant to Section 404(c) of the Clean Water Act, Pebble Deposit Area, Southwest Alaska* (the PD). EPA Region 10 solicited public comment on all issues discussed in the PD, including likely adverse impacts on fishery resources, mitigation measures to potentially address these impacts, and other options to restrict or prohibit potentially harmful discharges of dredged or fill material associated with mining the Pebble deposit.

Technical support is required in reviewing and responding to the public comments, technical studies, and data received on the PD. The goal of this effort is to facilitate EPA Region 10's ability to fully consider and respond to all public comments and issues raised as it decides whether to withdraw the PD or forward to EPA

Headquarters a recommended determination; to prepare and/or revise analyses related to the deposit site hydrology, fisheries, and site characteristics; and, if necessary, to produce the recommended and final determinations (these decisions are still pending).

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, to be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of fishery biology, hydrology, aquatic ecology, hardrock mine engineering, GIS, toxicology, physiology, chemistry, epidemiology, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: *EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP); *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*; and *Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data (attached here).*

Under this task, the Contractor shall perform other necessary communication activities related to management of the WA. Participation in weekly technical team calls and other discussions scheduled by EPA will also occur in conjunction with the tasks below.

Task 3: GIS Support

The Contractor shall conduct GIS-based calculations as needed in response to comments and technical studies received, including incorporation of new and/or revised data sources and map development. There are anticipated to be 3-5 sources of submitted information that will be in need of analysis. Specific tasks shall include revision of needed calculations and associated geospatial files related to update of the digital elevation model (DEM) used in the second draft Bristol Bay Watershed Assessment and/or Pebble Deposit 404c Proposed Determination. Examples of such revisions may include (but may not be limited to): updating subbasin delineations; creating or updating wetland maps; update of water balance, water chemistry, and pollutant transport calculations; creating or updating fish presence and distribution maps; and updating broad-scale habitat suitability metrics. Any creation of new or revisions to existing geospatial information shall be supported with metadata to ensure tracking of methodology and original sourcing in keeping with Federal Geographic Data Committee guidelines. Deliverables will include any final GIS layers and associated metadata, provided to EPA on DVD or other mutually acceptable format.

Task 4: New Data Analysis

The Contractor shall contribute to and assist with the development of Appendix A, which will evaluate 12 or more data sets highlighted in Exhibits 1 and 9 of comments submitted by Pebble Limited Partnership. As part of this task, the Contractor shall develop an annotated summary of the contents of the Pebble Limited Partnership's Environmental Baseline Document (~20,000 pages of summary material), to evaluate whether any additional data in this document warrant inclusion in Appendix A or any revisions to the PD. Deliverables will include final "print ready" versions of any developed text, figures, tables, graphs, or images, provided to EPA in PDF and editable formats.

Task 5: Response to Public Comments

The Contractor shall contribute to and assist with reviewing and responding to technical issues raised in the public comments on the PD. These reviews and responses may involve both textual and analytical support. Analytical support may include (but may not limited to): preparing annotated summaries of technical documents received; researching additional supporting documentation/citations; & reviewing/summarizing literature citations. Deliverables will include final "print ready" versions of any developed text, figures, tables, graphs, or images, provided to EPA in PDF and editable formats.

Task 6: Document Production

If EPA Region 10 decides to recommend a determination to EPA Headquarters and if EPA Headquarters subsequently decides to issue a final determination, the Contractor shall contribute to technical editing and document production of the Recommended Determination (RD) and Final Determination (FD). These activities may include (but may not be limited to): revising or creating any needed graphics, figures, or maps and their associated captions (particularly those affected by changes and activities under Tasks 2 through 4); technical editing of new or revised sections and appendices of the RD and FD; preparing the RD and FD for final "print-ready" release and printing; and technical editing of response to comments documents.

Task 7: File Archiving for the Bristol Bay Assessment and 404(c) Documents

The Contractor will support EPA in generating a complete, annotated archive of Bristol Bay Assessment and 404(c) documents. This support may include (but may not be limited to): completing metadata for GIS analyses and maps; annotating data spreadsheets and modeling runs; and organizing other relevant information suitable for use as an archive record.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]). The Contractor shall submit deliverables early if they are completed ahead of schedule. The schedule shown is based on our current understanding of the project schedule.

V. DELIVERABLES AND SCHEDULE

TASK	CALENDAR DAYS AFTER AWARD OF WA
Task 1. Initial Conference Call	3 days
Task 2. Staffing Plan, Work Plan and QAPP	20 days
Task 3. GIS Support	30 days
Task 4. New Data Analysis	30 days
Task 5. Response to Public Comments	90 days
Task 6. Document production	120 days
Task 7. Archiving	
• Bristol Bay Watershed Assessment	90 days
• 404(c) Documents	120 days

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.

2. The contractor shall comply with other applicable requirements for final WA reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the WA, and shall provide a bi-weekly update to the WAM by telephone for the duration of the WA, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this WA shall be sent to the PO.

Work Assignment Manager (WAM):

Christopher Hunter
U.S. EPA
Mail Code 4502T
Washington, DC 20460
(202) 566-1454
Hunter.Christopher@epa.gov

Alternate Work Assignment Manager (WAM):

Palmer Hough
U.S. EPA
Mail Code 4502T
Washington, DC 20460
(202) 566-1374

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

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Washington, DC 20460

Work Assignment

Work Assignment Number: 1-41

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Pebble Deposit Area

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	E Risk Assessment Support

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/12/2014 To 10/31/2015

Comments:
STOP WORK - EPA has received notice this afternoon, 12/4/14, from the judge in the Pebble Limited Partnership v. Environmental Protection Agency challenge under FACA that we must cease all 404(c) related activities until further notice.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Christopher Hunter (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1454 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name (Signature) 12/4/14 (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-42

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	SHC meetings support
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E Risk Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/20/2015 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Melissa Mccullough (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-5646 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-42

Title: Sustainable and Healthy Communities Research Program (SHC) meetings support

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Specify Section & Paragraph SOW: E Risk Assessment Support

PERIOD OF PERFORMANCE: *CO award through 10/31/2015*

PERIOD OF PERFORMANCE: Option 1: Award thru October 31, 2015

I. PURPOSE:

The purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) Immediate Office of the Assistant Administrator (IOAA), Office of Research and Development (ORD), in the completion of providing administrative and logistical/facilitation support services for the annual SHC Communique and Stakeholders meeting. The two meetings are being done in conjunction, and will be held in the Potomac Yard EPA location in the Washington, DC area. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001, Section E. Risk Assessment Support of the HHRA PWS.

II. BACKGROUND:

SHC was designed to be a solution-oriented, community-focused research program, which needed to integrate across multiple disciplines and multiple ORD lab/centers. This novel nature of SHC work needs significant intra-program communication to best utilize the talents of scientists, as well as the intellectual and logistical resources of the labs and centers. In addition, our work must be grounded in regular communication with our internal EPA Partners and our community and NGO stakeholders, in order to make sure that our products are relevant, timely, and usable. For this purpose, SHC has instituted two meetings, to be held again in April of 2015 – the Communique for our partners, and the Stakeholders meeting. These two meetings will be coordinated -- held in the same week and location, possibly with overlapping sessions. An important and popular part of these meetings will be a tools demonstration session. It will likely be a ½ day session, with approximately 10 – 20 tools being demonstrated, each of which will have unique AV needs.

The timing of the Communique/Stakeholders meetings are critical, in that SHC will be developing both the SHC Strategic Research Action Plan 2012-2016 (StRAP) as well as detailed research plans for newly identified projects. In order to focus staff attention on the critical content of these two meetings, SHC is looking for logistical support for the meetings.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for two adjacent meetings supporting the SHC research program. Support will include planning for meeting and logistics, onsite meeting support and facilitation, and may include communication activities related to

the meetings such as save the date notices or registration. The program's meetings are scheduled for the week of April 6-10, 2015 at EPA's Potomac Yard facility in Arlington, VA EPA anticipates the Communique meeting to have approximately 100 – 150 participants. We hope for the stakeholder meeting to have 20 - 30 participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has reserved its own meeting room space for these meetings per EPA requirements. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions necessary to draft a workplan that will outline tasks, deliverables and due dates. Develop and provide work plan. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.

2. Pre-meeting support: Administrative and logistical support services for each meeting may include:

    - Develop a registration mechanism and coordinating registration, including maintaining a list of participants.
    - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
    - Preparation and distribution of meeting materials including final agenda, meeting roster, name badges and other meeting materials.
    - Working with those ORD staff who will be demonstrating tools for the meetings, assessing AV, space, power and other needs.
    - Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computers, projectors, screen, flip charts, tape, markers etc., including working with SHC staff and onsite facility staff to arrange appropriate space, AV and logistical needs for Tools demonstrations.
    - Setting up any identified webinar and conference call capability for remote participation.

3. Onsite Logistical Support and Reporting

    - Providing staff to support the meeting onsite.
    - Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
    - Manage speaker and tools demonstration presentations to ensure presentations are loaded to the appropriate laptop, being projected adequately and available following the event.
    - Update attendee list at the end of the workshop (remove no-shows, add walk-ins).
    - Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations that arise, such as those related to AV support or break-out room set-up.

4. Follow-up Meeting Support

    - Post materials to event webpage.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Initial contact (listed above) shall be performed.	Within 3 days of award
Establish website for on-line registration	60 days prior to the meetings
Submit electronic copies of registration lists and registration materials;	On request during planning, with the final submitted the Friday before the Communique
Submit updated list of registered attendees (including walk-ins), electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following each meeting

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.
Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel).

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green

Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Contracting Officer Representative (WA-COR)
Melissa McCullough
919-541-5646
Mccullough.melissa@epa.gov

Alternate Work Assignment Contracting Officer Representative (Alt-WA-COR)
Linda Lassiter
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lassiter.linda@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-42

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	SHC meetings support
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E. Risk Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
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- [ ] Incremental Funding

Period of Performance: From 01/20/2015 To 10/31/2015

Comments:

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Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$19,164.00	175
Total:	$19,164.00	175

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 02/16/2015	$19,164.00	175
Cumulative Approved:	$19,164.00	175

Work Assignment Manager Name: Melissa Mccullough (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-5646 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

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Washington, DC 20460

Work Assignment

Work Assignment Number: 1-43

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Dibutyl Phthalate
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:
Technical editing and augmenting evidence tables and exposure response arrays for Dibutyl Phthalate (CASRN: 84-74-2)

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Xabier Arzuaga (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8634 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-43

TITLE: Technical editing and augmenting evidence tables and exposure response arrays for Dibutyl Phthalate (CASRN: 84-74-2)

Specify Section & Paragraph SOW: A. Assessment Issues and Documents
1. Human Health Assessment Documents; E. Risk Assessment Support; F. Information Management

PERIOD OF PERFORMANCE: *CO award to 10/31/2015*

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of revisions to the draft IRIS Toxicological Review of *Dibutyl Phthalate (DBP).* The overall objective of this WA is to obtain support from ICF in augmenting the evidence tables and technical editing the exposure response arrays for the IRIS *Toxicological Review of Dibutyl Phthalate (DBP).* This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

IRIS is an EPA data base containing Agency scientific positions on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemicals in the environment. IRIS currently provides health effects information on over 500 chemical substances.

IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

EPA holds bimonthly public meetings to provide an opportunity for input and discussion on preliminary materials for IRIS chemicals prior to the development of the assessments. The objective of this public meeting is to obtain input from stakeholders and the public on the studies and data that may be used to characterize hazard and exposure-response relationships and to develop toxicity values. Specifically, EPA is seeking input on preliminary materials including draft literature searches and associated search strategies, evidence tables, and exposure-response arrays for chemicals prior to the development of the IRIS assessments.

The overall goal of the human health risk assessments is to provide scientifically-defensible reasoning for the choice of critical cancer and non-cancer effects due to chemical exposure, along with the literature and principal study(ies) that best represent and support that choice. The Work Assignment Manager (WAM) will provide technical direction as necessary.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5),*" http://www.epa.gov/quality/qs-docs/r5-final.pdf; and "*A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*" and its Addendum, http://www.epa.gov/stpc/assess.htm. The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3: Updating and augmenting evidence tables and formating the exposure response arrays for *Toxicological Review of Dibutyl Phthalate (DBP).* Create evidence tables with data from DBP metabolite (~40) and mechanistic (~240) studies identified in literature search. Update existing evidence tables for animals studies according to format used to develop evidence tables for the Toxicological Review of Butyl Benzyl Phthalate (BBP). Technical editing of the exposure response arrays may include: standardizing symbols; verifying and restyling reference citations where required; cross-checking information in the exposure response arrays as well as correcting errors in grammar, spelling, and punctuation. Work in this task shall be performed according to EPA guidance related to the technical editing and preparation for publication of Toxicological Reviews, the draft Handbook for IRIS Assessment Development and the current version of the evidence table template. The Handbook for Preparing EPA Documents shall be used as a primary reference to resolve issues involving usage and style. Specifically, this task includes:

a. Create new evidence tables for DBP metabolite studies – Extract data from DBP metabolite studies (~40) and create new evidence tables. QA tables developed.

b. Summarize the mechanistic studies (~240) identified in the literature – Develop a table including information on the model system and specific assays used, route evaluated, general target tissues or systems studied, and endpoints reported. QA tables developed.

c. Update and edit existing evidence tables for format – Update format of DBP evidence according to template and style used to develop evidence tables for the Toxicological Review of Butyl Benzyl Phthalate (BBP).

d. Update, augment, and edit exposure response arrays – Add data from studies identified in literature search updates and missing study data as well as correct exposure response array format and style. Technical editing of text in exposure response array.

e. HERO links – Ensure that HERO links are functional in the revised work product. When necessary, add citations to the evidence tables using LitCiter. When using LitCiter, only use the HERO DBP library titled "Di-n-Butyl Phthalate (DBP)".

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	Per contact requirements
Task 3. Update evidence tables, reformat exposure response arrays, develop mechanistic and metabolite tables	Approximately 2 weeks after EPA's submission of the document to ICF

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Xabier Arzuaga
Telephone: 703-347-8634
Fax: 703-347-8689
e-mail: arzuaga.xabier@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Mail Code 8601-P
Washington, DC 20460

Overnight Delivery location:
Two Potomac Yard (North Building)
2733 S. Crystal Drive
Arlington, VA 22202

Alternate Work Assignment Manager:

James Weaver
Telephone: 919-541-1545
Fax: 919-541-5078
e-mail: Weaver.James@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Overnight Delivery location:
U.S. EPA
MD B243-01
4930 Old Page Road
Durham , NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-43

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Dibutyl Phthalate
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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4										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$36,549.00	379
Total:	$36,549.00	379

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 01/05/2015	$36,549.00	379
Cumulative Approved:	$36,549.00	379

Work Assignment Manager Name: Xabier Arzuaga (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8634 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-44

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Decontamination Conf.
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E2, Risk Assessment Support; Administration and Te

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/20/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
This Action:	11/01/2013 To 10/31/2015		
Total:			

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Lukas Oudejans (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2973 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-44 -

TITLE: Support to the 2015 EPA International Decontamination Research and Development Conference

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Specify Section & Paragraph SOW: E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: *CO award to 10/31/15*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) for administrative and technical support to the EPA International Decontamination Research and Development Conference, hosted by EPA's National Homeland Security Research Center (NHSRC).

The desired goals of the conference are the following:

- To bring together researchers, responders, U.S. and international government and private stakeholders in CBR remediation and recovery preparedness;
- To facilitate the exchange of information on scientific endeavors, including applied research, field demonstrations, guidance and tool development and field applications related to CBR remediation issues; and,
- To demonstrate the connection between basic or fundamental decontamination research and applied research, as well as applied research and effective field application.

The work assignment has two major components: (1) the preparation and implementation of a three day conference to take place on May 5-7, 2015, at the EPA RTP campus in North Carolina; (2) the preparation of a post-conference report that compiles the abstracts and presentations along with an executive summary of the conference. This work assignment includes the following major deliverables:

1. Assistance and coordination with a three day conference as noted in the tasks.
2. Administrative and Technical support for the three day Decontamination R&D Conference.
3. Post-conference summary report.
4. Assistance with plenary speaker and three other outside participants.

II. BACKGROUND

Since 2004, NHSRC has organized and hosted an international conference on decontamination research and development. Decontamination is one of the critical challenges that the United States and EPA would face in recovering from a major chemical, biological, or radiological incident.

The conference is designed to facilitate presentation, discussion, and further collaboration on research and development focused on an all-hazards approach to cleaning up contaminated buildings (both interior and

exterior), infrastructure, and other areas/materials. The conference continues to focus strongly on matters involving chemical, biological, and radiological (CBR) threat agents.

Topics of interest for this conference include:
- New research data, or field activities and large scale demonstrations related to the detection and decontamination of biological (including agricultural threat agents and biotoxins), chemical, and radiological threat agents in indoor (in facilities) or outdoor areas/materials
- Cross cutting topics related to restoration including: clean-up levels/risk assessment, exposure assessment, sampling/analysis of threat agents, fate/transport/containment, material compatibility with decontamination processes, tool and guidance development, waste management of threat agent-contaminated materials, water/wastewater decontamination, and systems approach to response and regulatory issues.

Invitees include persons involved in CBR remediation and recovery research, individuals such as EPA On-Scene Coordinators who conduct remediation activities, people involved in setting policy related to CBR decontamination in the U.S. and abroad, as well as individuals from academia and industry.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference.

Task 3: PRE-CONFERENCE PREPARATION

Task 3.1. Conference Abstract Collection:

The contractor shall setup an email account to receive abstracts as submitted by participants. The email address shall reflect the intended purpose of this conference. The Contractor shall receive conference abstracts following the initial call for abstracts by the conference organizers.

The Contractor shall compile received abstract titles and prepare a spreadsheet to facilitate EPA review of abstracts and placement in the conference program following acceptance by EPA of the presentation.

Task 3.2. Pre-registering Conference Participants:

The Contractor shall setup a registration site for all participants. The registration process shall include obtaining information whether the registrant is a United States citizen or permanent resident, identification of research area, selection of preferred presentation mode (oral vs poster presentation), and which part of the contact information can be made available to (a) other registrants of the conference and (b) the general public as part of the post conference report. Upon receipt of a registration request,

the Contractor shall determine if the registrant belongs to the list of invitees as provided by the EPA WAM. If not, the Contractor shall contact the WAM on whether to accept or decline the registration. The Contractor shall confirm a successful registration with the registrant.

The Contractor shall provide a spreadsheet of pre-registrants 4 weeks prior to the conference, and again beginning each week thereafter until the start of the conference, unless there were no new pre-registrants added during that period. The Contractor should also include in the on-line pre-registration information a list of local hotels and other pertinent logistical information.

Task 3.3. Other Pre-Meeting Logistical Activities (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support):

The Contractor shall, when given a list of potential speakers, moderators, key audience members and other audience categories, secure release forms for presentations by all speakers for both upload onto an ftp site and for publication in the conference report, obtain their appropriate power point presentations and organize these presentations in an appropriate matter to be ready to load onto EPA computers at the conference. The Contractor will confirm moderator participation in cooperation with the WAM. The Contractor shall also provide other necessary logistical support for presenters and attendees including directions to the conference and coordination of presentation materials.

The Contractor shall coordinate with the EPA AV support personnel in RTP in advance of the conference to ensure that proper AV equipment is available (microphones, laptops and projectors). EPA has secured meeting space at the EPA facilities on the RTP, NC campus. The Contractor shall serve as the lead point of contact to insure the adequate flow of all activities on the days of the conference and coordinate the speakers and overall participation of other representatives.
The Contractor shall be available for on-site registration as necessary, provide any copies of EPA relevant meeting material and allow sufficient space at the entry table for speakers and participants to leave relevant information for pick-up at the time of on-site registration. The Contractor shall coordinate registration near the main meeting room.

Task 3.4. Preparing Conference Materials:

The Contractor shall prepare information materials in a conference Information Packet. The packet shall include announcements and a final conference agenda. The Contractor shall provide a list of overall participants and presenters, their contact information, and Bios of presenters. The Contractor shall include this information in a Conference Information Packet and make these packets available in sufficient numbers to provide each participant with a packet at the time of on-site registration.

TASK 4: DURING-CONFERENCE RESPONSIBILITIES

Task 4.1. Conference Registrations:

The on-site Contractor support shall include manning the registration table, providing participant name tags and conference information packets, providing EPA handouts and allowing space for other information provided by speakers ahead of time and signing in registrants.

Task 4.2. Conference IT Logistics:

The EPA will provide laptop computers. The Contractor shall coordinate with the WAM to ensure that all presentations are loaded onto EPA computer.

TASK 5: CONFERENCE INVITED SPEAKER TRAVEL

Task 5.1. Invited Speaker Travel:

The Contractor shall identify 1 international and 3 domestic scientists to be invited speakers at the conference. The Contractor shall then coordinate logistics and pay for their travel. The Contractor shall anticipate that the speakers will attend the entire Conference.

TASK 6: POST-CONFERENCE

Task 6.1. Conference Report:

The Contractor shall prepare an electronic document that compiles all presentations, abstracts, speaker question and answer sessions and an executive summary into a single PDF and Microsoft Word file. The draft conference report will include the agenda, a complete list of actual attendees and their contact information as agreed upon during the registration process.

Task 6.2. Power Point Presentations:

The Contractor shall post the released presentations onto an ftp site that can be accessed by the conference participants.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., MS Office 2010 (or later) spreadsheets and documents.

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Work, Staffing Plan	20 days after award
Task 3. List of Abstracts List of Registrants Conference Information Packets	March 1, 2015 4 weeks prior to conference and weekly up to conference date May 5, 2015
Task 4. Conference Materials	May 5, 2015
Task 5. List of Invited Speakers	March 1, 2015
Task 6. Draft Conference Report Final Conference Report	Within 5 weeks of conference conclusion Within 20 business days after receipts EPA comments to draft

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Lukas Oudejans
U.S. EPA, ORD/NHSRC
109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2973
oudejans.lukas@epa.gov

Alternate WAM:

Tanya Medley
U.S. EPA, ORD/NHSRC
109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2336
medley.tanya@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-44

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Decontamination Conference
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E2. Risk Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/20/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$48,819.00	515
Total:	$48,819.00	515

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 12/11/2014	$48,819.00	515
Cumulative Approved:	$48,819.00	515

Work Assignment Manager Name: Lukas Oudejans (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2973 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-44

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Conference
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: : E2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/20/2014 To 10/31/2015

Comments:
Support to the 2015 EPA International Decontamination Research and Development Conference

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Lukas Oudejans (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2973 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

AMENDMENT 1 TO
PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-44

TITLE: Support to the 2015 EPA International Decontamination Research and Development Conference

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Specify Section & Paragraph SOW: E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: *CO award to 10/31/15*

I. PURPOSE OF AMENDMENT 1

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) for administrative and technical support to the EPA International Decontamination Research and Development Conference, hosted by EPA's National Homeland Security Research Center (NHSRC).

This amendment identifies two additional tasks that were not incorporated in the initial PWS. The first additional task (Task 3.3A1) identifies the initialization and maintenance of an Adobe Connect webinar option during the Decon Research and Development conference for a limited number of participants who are not able to attend the conference in person. The second task (split over Task 4.1A1 and Task 4.3A1) describes the logistical support by the contractor of a quarterly meeting that will be held immediately following the end of the conference. EPA will host this quarterly Underground Transportation Restoration (UTR) meeting.

The main purpose of the PWS remains unchanged.

II. BACKGROUND

No changes to the background of the 2015 EPA International Decontamination Research and Development Conference.

Background on the quarterly UTR meeting: EPA provides in-kind support and has an Interagency Agreement with the Department of Homeland Security (DHS) under this UTR project. The quarterly meeting has been scheduled to follow the 2015 EPA International Decontamination Research and Development Conference since there is a significant overlap in research area and attendees of both meetings. Previous quarterly meetings were hosted by Lawrence Livermore National Laboratories.

III. STATEMENT OF WORK

Task 1: Establish Communication

No changes

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a revised Technical Work Plan describing how the additional work outlined in this Performance Work Statement Amendment will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a revised Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference.

Task 3: PRE-CONFERENCE PREPARATION

Task 3.1. Conference Abstract Collection:

No changes

Task 3.2. Pre-registering Conference Participants:

No changes

Task 3.3. Other Pre-Meeting Logistical Activities (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support):

No changes

NEW Task 3.3A1. Additional Pre-Meeting Logistical Activities

The Contractor shall coordinate with the EPA AV support personnel in RTP in advance of the conference to ensure that two additional laptops are available to host Adobe Connect webinars in two conference rooms. The Contractor shall coordinate with EPA AV support personnel the presence of two phone lines for audio support to the webinars. The Adobe Connect webinars will be hosted by EPA. EPA will setup the Adobe Connect Room and disseminate contact information to intended participants of the webinar option. Both Adobe Connect and phone lines shall also be available during the UTR quarterly meeting immediately following the Decontamination Conference. The Adobe Connect webinars for the UTR quarterly meeting will be hosted by EPA. EPA will setup the Adobe Connect Room and disseminate contact information to intended participants of the webinar option for the UTR quarterly meeting.

Task 3.4. Preparing Conference Materials:

No changes.

TASK 4: DURING-CONFERENCE RESPONSIBILITIES

Task 4.1. Conference Registrations:

No changes.

NEW Task 4.1A1. UTR Meeting Registrations:

The on-site Contractor support shall facilitate the registration to the UTR quarterly meeting, providing participant's name tags to the UTR Quarterly meeting. This meeting will end at lunch time on Friday, May 8.

Task 4.2. Conference IT Logistics:

The EPA will provide laptop computers. The Contractor shall coordinate with the WAM to ensure that all presentations are loaded onto EPA computer.

NEW Task 4.3A1. Conference Adobe Connect Webinar Logistics:

The Contractor shall initiate the Adobe Connect webinar at the start of each day of the conference and record the names of webinar participants throughout the day. The Contractor shall follow the slide presentations from all presenters and monitor the Adobe Connect chat function for reported technical difficulties or questions to the presenter. Webinar attendees will have the option to submit questions via the Adobe Connect chat function. The Contractor shall monitor the chat room for questions and potential communication difficulties. Technical difficulties shall be communicated to AV support personnel for further troubleshooting.

TASK 5: CONFERENCE INVITED SPEAKER TRAVEL

Task 5.1. Invited Speaker Travel:

No changes.

TASK 6: POST-CONFERENCE

Task 6.1. Conference Report:

No changes.

Task 6.2. Power Point Presentations:

No changes.

IV. ANTICIPATED DELIVERABLES

No changes.

V. DELIVERABLES AND SCHEDULE

No changes. Deliverables schedule remains as follows:

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Work, Staffing Plan	20 days after award
Task 3. List of Abstracts List of Registrants Conference Information Packets	March 1, 2015 4 weeks prior to conference and weekly up to conference date May 5, 2015
Task 4. Conference Materials	May 5, 2015
Task 5. List of Invited Speakers	March 1, 2015
Task 6. Draft Conference Report Final Conference Report	Within 5 weeks of conference conclusion Within 20 business days after receipts EPA comments to draft

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Lukas Oudejans
U.S. EPA, ORD/NHSRC
109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2973
oudejans.lukas@epa.gov

Alternate WAM:

Tanya Medley
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919-541-2336
medley.tanya@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-44

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Decontamination Conference
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E2. Risk Assessment Support

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/20/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$66,679.00	721
Total:	$66,679.00	721

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 03/30/2015	$66,679.00	721
Cumulative Approved:	$66,679.00	721

Work Assignment Manager Name: Lukas Oudejans (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2973 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-45

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Water Clusters
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A. Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Julius Enriquez (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7285 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-45

TITLE: Strengthening EPA's Collaboration with Water Clusters

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO approval through 10/31/15

BACKGROUND:

EPA researchers are leading the way in developing cutting-edge technologies to help solve many of the current environmental problems. One approach has been to develop public-private partnerships focused on environmental technology innovation and commercialization, while supporting regional economic development efforts. In early 2010, EPA took the lead for a program that would drive such an effort, known as a cluster. As drivers of innovation, clusters play an important role in addressing the nation's pressing environmental issues. EPA supports the development of clusters and other technology innovation efforts through its Environmental Technology Innovation Clusters Program. The Clusters Program communicates with environmental technology cluster organizations across the nation, and periodically arranges calls and meetings where cluster organizers can share best practices with each other and establish cooperation between clusters.

Objective:

The objective of this Performance Work Statement is to support of EPA's *Goal 2: Protecting America's Water.* The PWS main goals are to help EPA in

- Establishing its role nationally to support and collaborate with both local and the national water clusters. An example of a local cluster is the Cincinnati/Dayton/ NKy/SE IN water clusters which includes Confluence.
- Strengthening the capacity of water cluster organizations through collaborations and technical support.

EPA is focusing on developing new targeting tools to strengthen our partnerships with non-government organizations and private companies committed to supporting local efforts to improve and protect the environment through a combination of traditional and innovative strategies.

<u>Technical Consultants/Team Qualifications</u>

The ideal consultant/team:

- Should preferably have three years national and international experience with clusters, technology based economic development initiatives and/or similar business/technology development groups. Experience should include designing and building business/technology groups/networks/hubs/clusters and helping them foster and mature over several years. The experience should include an understanding of the phases, dynamics and changes that clusters will experience as they mature.
- Should be able to demonstrate knowledge and understanding in the success, weakness, opportunity and

threats of business/technology clusters/groups/networks/hubs.

- Should understand and have experience with identifying the regional cluster's economic structure such as infrastructure, human resources, linkages, regulatory policies, and access to technology and financial resources. It is important that EPA become familiar with the key economic metrics that would help in maintaining a sustainable cluster hub.
- Should have experience in effectively communicating to EPA and its stakeholders the strategies and best practices for a sustainable national water cluster

TECHNICAL SUPPORT

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, Call Schedule

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule (including regular calls), budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas required to complete this WA.

Task 3. The contractor shall provide technical support and consultation to the EPA ORD Clusters Program. This shall be accomplished by:

- providing training and advice to the EPA ORD Cluster Program leaders on relevant information that can be used in the formulation and implementation of cluster activities e.g. value propositions and strategies with both the local and national water clusters.
- revaluating and developing best practices to strengthen EPA's role and strategy with the local Cincinnati/Dayton/ NKy/SE IN, including Confluence and the national water clusters.
- helping EPA develop outreach programs to local and national water clusters. Examples: webinars, training, and development of other communication materials such as brochures, information briefs, slides

Task 4. The contractor shall help EPA identify the important economic structures that are needed to develop a successful and sustainable cluster, locally and nationally. Some of the economic structures may include infrastructure, human resources, linkages, regulatory policies, access to foreign markets with the help of DOC-USCS and access to technology and financial resources. It is important that EPA become familiar with the key economic metrics that would help in maintaining a sustainable cluster hub.

Task 5. The contractor shall develop metrics and/or tools

- that can be used to prioritize activities, monitor and evaluate EPA's collaborative networking role with local water clusters in the Cincinnati/Dayton/ NKy/SE IN region which includes Confluence and the various national regional water clusters
- that can be used to determine successful cluster organization outcomes in both the Cincinnati/Dayton/ NKy/SE IN regional water cluster, including Confluence, the water cluster organization, and in the national water cluster network.

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Call schedule	15 days after award Regular calls throughout WA
Task 3. The contractor shall provide technical support and consultation to the EPA ORD Clusters Program	30 days after the award
Task 4. EPA identify the important economic structures	30 days after the award
Task 5. develop metrics and/or tools	45 days after the award

Note: All days are calendar days.

Monthly Reports

The monthly reports shall:

- summarize the work accomplished and milestones and deliverables achieved under all the individual tasks as per the work plan
- summarize the planned activities anticipated for the upcoming period
- identify problems and resolutions encountered
- be used to evaluate the status and the progress of the work
- be used to resolve technical and/or budgeting problems, and
- Identify and demonstrate expenditures.

Work Assignment Meetings and Reports

Project meetings shall be conducted once per month or as often as needed by the WACOR with advice from the technical coordinator to assure the completion of the efforts. The meeting schedule can be changed by mutual agreement. The contractor shall provide at a minimum the following at each meeting:

- status and progress of the technical and consultation support efforts
- planned activities for the upcoming period
- problems encountered and resolutions
- budget information.

The contractor shall summarize project meetings and submit summary to the EPA CL-COR and WACOR within five (5) working days of the project meeting. The submitted report shall be in an agreed-upon format. Report shall be provided via E-mail.

Draft Summary Reports

The contractor shall submit to the EPA three (3) quarterly summary reports of the consultation efforts on the technology transfer tasks and the EPA cluster task. The report shall document the path of discovery and include: title, update status, path forward, and recommendations & observations. The first quarterly report shall be provided to the EPA WAM 30 calendar days after the completion of the first quarter.

Final Reports

A final report of the consultation efforts summarizing all four (4) quarters shall be provided within 30 calendar days of the completion of the level of effort.

The final report will discuss EPA's role and how it could effectively work locally and nationally with the various regional water cluster organizations. This report will also focus and describe the experience and lessons

learned from EPA's collaboration with the Cincinnati/Dayton/ NKy/SE IN regional water cluster, including Confluence, the cluster organization. The final report shall

- Have an ecosystem map and description of the various water-related technology clusters being proposed nationally. The report will also include a review of the local water technology cluster ecosystem map in Cincinnati/Dayton/ NKy/SE IN and if needed, a revised/updated map will be included in the report.
- Identify the main strengths and weaknesses, threats, challenges, successes, and opportunities for EPA's collaboration with both the local regional water clusters and the national water technology cluster organizations. Cultivate the lessons learned from these analyses into recommendations to EPA for effectively collaborating and networking with the various national water technology cluster organizations.
- Provide EPA with best practices to effectively collaborate with both local and the national water technology cluster organizations using the concept of structured interactions between industry, research universities, and government.
- Identify the important economic structures needed for successful and sustainable national water technology cluster organizations. Examples of these economic structures are infrastructures, human resources, linkages, regulatory policies, and access to technology and financial resources.
- Identify metrics that can be used to prioritize activities, monitor and evaluate EPA's collaboration and networking role with local and the various national water technology cluster organizations.
- Identify metrics that can be used to determine successful cluster organization outcomes, such as those being used by the US Small Business Administration.

Below is the suggested outline for the final report.

- Title;
- executive summary;
- background;
- objective;
- relevance;
- best practices; and
- strategies, milestones, recommendations, metrics
- observations and references.

Outreach

A month after submitting the final report, the contractor shall present to EPA and its water cluster partners via webinar a summary of the key findings of the final report. The webinar shall discuss:

- the ecosystem map and description of the various water-related technology clusters being proposed nationally.
- the main strengths and weaknesses, threats, challenges, successes, and opportunities for EPA's collaboration with both the local regional water clusters and the national water technology cluster organizations and lesson learned from this analyses.
- the best practices to implement for EPA to effectively collaborate with water technology cluster organizations.
- the important economic structures needed for successful and sustainable national water technology cluster organizations.

- the metrics that can be used to prioritize activities, monitor and evaluate EPA's collaboration and networking role with local and the various national water technology cluster organizations.

MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

WAM

Julius Enriquez
U.S. Environmental Protection Agency
National Risk Management Research Laboratory
Cincinnati, Ohio 45268
Phone: 513-569-7285
email: Enriquez.julius@epa.gov

Alternate WAM

Evelyn Hartzell
U.S. Environmental Protection Agency
National Risk Management Research Laboratory
Cincinnati, Ohio 45268
Phone: 513-569-
email: hartzell.evelyn@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-45

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Water Clusters
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Julius Enriquez (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7285 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-45
Amendment #1

TITLE: Strengthening EPA's Collaboration with Water Clusters

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO approval through 10/31/15

BACKGROUND:

EPA researchers are leading the way in developing cutting-edge technologies to help solve many ~~of the~~ current environmental problems. One approach has been to develop public-private partnerships focused on environmental technology innovation and commercialization, while supporting regional economic development efforts. In early 2010, EPA took the lead for a program that would drive such an effort, known as a cluster. As drivers of innovation, clusters play an important role in addressing the nation's pressing environmental issues. EPA supports the development of clusters and other technology innovation efforts through its Environmental Technology Innovation Clusters Program. The Clusters Program communicates with environmental technology cluster organizations across the nation, and periodically arranges calls and meetings where cluster organizers can share best practices with each other and establish cooperation between clusters.

Objective:

The objective of this Performance Work Statement is to support ~~of~~ EPA's *Goal 2: Protecting America's Water*. The PWS main goal is~~goals are~~ to help EPA in:-

-

- developing a value proposition for the USEPA, ORD Water Clusters Program
- disseminating this value proposition to the different water sector industries by conducting a webinar.
- ~~Establishing its role nationally to support and collaborate with both local and the national water clusters. An example of a local cluster is the Cincinnati/Dayton/ NKy/SE IN water clusters which includes Confluence.~~
- ~~Strengthening the capacity of water cluster organizations through collaborations and technical support.~~

~~EPA is focusing on developing new targeting tools to strengthen our partnerships with non-government organizations and private companies committed to supporting local efforts to improve and protect the environment through a combination of traditional and innovative strategies.~~

Should preferably have three years national and international experience with clusters, technology based
Technical Consultants/Team Qualifications

The ideal consultant/team:

- economic development initiatives and/or similar business/technology development groups. Experience should include developing effective value propositions for technology business clusters, designing and

building business/technology groups/networks/hubs/clusters and helping them foster and mature over several years. The experience should include an understanding of the phases, dynamics and changes that clusters will experience as they mature.

- ~~•~~ Should be able to demonstrate knowledge and understanding of~~in~~ the success, weakness, opportunity of and threats to~~of~~ business/technology clusters/groups/networks/hubs. -
- Should understand and have experience with identifying the regional cluster's economic structure such as infrastructure, human resources, linkages, regulatory policies, best practices for a sustainable national water cluster. and access to technology and financial resources~~. It is important that EPA become familiar with the key economic metrics that would help in maintaining a sustainable cluster hub.~~

TECHNICAL SUPPORT

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, Call Schedule

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule (including regular calls), budget, and level of effort. Contractor shall provide a description of the development process and the methodology they would use to develop the value propositions for each of the sectors mentioned below. The Contractor shall also prepare a Staffing Plan, (~~which shall be~~ submitted as part of the Work Plan)~~,~~ that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic ~~science~~ areas required to complete this WA.

Task 3. The contractor shall assist EPA in developing a value proposition for the USEPA, ORD Water ~~provide technical support and consultation to the EPA ORD~~ Clusters Program. This task would also include tailored~~shall be accomplished by:~~

~~providing training and advice to the EPA ORD Cluster Program leaders on relevant information that can be used in the formulation and implementation of cluster activities e.g.~~ value propositions depending upon who the USEPA, ORD Water Clusters Program is collaborating~~and strategies~~ with. Below are the different sectors that would require tailored value propositions: ~~both the local and national water clusters.~~

a. Interagency offices within the EPA, e.g OW, OICA, OPPT, OCG and ORD's NPD
b. Water clusters – developing or developed in various parts of the US
c. Large Business in the water sector industries
d. Small Business in the water sector industries
e. Water Programs within State Environmental Protection Agencies or State Public Health Agencies with explicit jurisdiction over water programs
f. Other Federal Agencies (DOC, SBA at a minimum)
g. Universities and other research institutions
h. Water utilities and their sector representative organizations and consultants
i. Entrepreneurs and other organizations that support water technology innovation

Task 4. Conduct webinars for EPA Clusters Program staff and water cluster leaders to share the results of this effort.

- ~~revaluating and developing best practices to strengthen EPA's role and strategy with the local Cincinnati/Dayton/ NKy/SE IN, including Confluence and the national water clusters.~~

- ~~helping EPA develop outreach programs to local and national water clusters. Examples: webinars, training, and development of other communication materials such as brochures, information briefs, slides~~

~~**Task 4**. The contractor shall help EPA identify the important economic structures that are needed to develop a successful and sustainable cluster, locally and nationally. Some of the economic structures may include infrastructure, human resources, linkages, regulatory policies, access to foreign markets with the help of DOC-USCS and access to technology and financial resources. It is important that EPA become familiar with the key economic metrics that would help in maintaining a sustainable cluster hub.~~

~~**Task 5.** The contractor shall develop metrics and/or tools~~

- ~~that can be used to prioritize activities, monitor and evaluate EPA's collaborative networking role with local water clusters in the Cincinnati/Dayton/ NKy/SE IN region which includes Confluence and the various national regional water clusters~~
- ~~that can be used to determine successful cluster organization outcomes in both the Cincinnati/Dayton/ NKy/SE IN regional water cluster, including Confluence, the water cluster organization, and in the national water cluster network.~~

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after receipt~~award~~ of amended PWS~~Work Assignment~~
Task 2. Submit a work plan ~~Call schedule~~	10 business~~15~~ days after receipt of amended PWS~~award~~ ~~Regular calls throughout WA~~
Task 3. Assist EPA in developing a value proposition	10 business days after approval of WP
Task 4. Webinar a. Preliminary webinar dry run with USEPA, ~~3. The contractor shall provide technical support and consultation to the EPA~~ ORD Water Clusters Program. Conduct for EPA Clusters Program staff and water cluster leaders to share the results of this effort.	August 17, 2015 September 27, 2015~~30 days after the award~~
~~Task 4. EPA identify the important economic structures~~	~~30 days after the award~~
~~Task 5. develop metrics and/or tools~~	~~45 days after the award~~

Note: All days are calendar days unless specified.

Monthly

~~Monthly~~ Reports

The first monthly report shall be delivered 30 days after approval of the work plan. The monthly reports shall:

- summarize the work accomplished and milestones and deliverables achieved under all the individual tasks as per the work plan
- summarize the planned activities anticipated for the upcoming period
- identify problems and resolutions encountered
- be used to evaluate the status and the progress of the work

- be used to resolve technical and/or budgeting problems, and
- Identify and demonstrate expenditures.

Work Assignment Meetings and Reports

The first project meeting shall be held 10 days after approval of the WP. Project meetings shall be conducted once per month or as often as needed by the WACOR with advice from the technical coordinator to assure the completion of the efforts. The meeting schedule can be changed by mutual agreement. The contractor shall provide at a minimum the following at each meeting:

- status and progress of the technical and consultation support efforts
- planned activities for the upcoming period
- problems encountered and resolutions
- budget information.

The contractor shall summarize project meetings and submit summary to the EPA CL-COR and WACOR within five (5) working days of the project meeting. The submitted report shall be in an agreed-upon format. Report shall be provided via E-mail.

Draft Summary Reports

The contractor shall submit within 90 days after work plan approval to the EPA a draft report. ~~.three (3) quarterly summary reports of the consultation efforts on the technology transfer tasks and the EPA cluster task.~~ The report shall ~~document the path of discovery and~~ include: title, update status, path forward, and recommendations & observations. The draft~~first quarterly~~ report shall:

- Discuss USEPA, ORD Water Clusters Program's value propositions with the different sectors (as defined in Task 3) in the water industry.
- Discuss the various methods and processes used ~~be provided~~ to develop these value propositions.
- Describe the measurable gains and outcomes for a specific water industry sector (as defined in Task 3) from USEPA, ORD Water Clusters Program's products and services.

Final Report

The contractor shall submit the ~~**Reports**~~

- Discuss USEPA, ORD Water Clusters Program's final value propositions with the different sectors (as defined in Task 3) in the water industry.
- Discuss the various methods and processes used to develop the different value propositions and how these methods and processes can be used by EPA to develop or improve on its value propositions.
- List the USEPA, ORD Water Clusters Program's major products and services that support the value proposition for each of the sectors.
- Describe the measurable gains and outcomes for a specific water industry sector (as defined in Task 3) from USEPA, ORD Water Clusters Program's products and services.

~~The final report will discuss EPA's role and how it could effectively work locally and nationally with the various regional water cluster organizations. This report will also focus and describe the experience and lessons learned from EPA's collaboration with the Cincinnati/Dayton/ NKy/SE IN regional water cluster, including Confluence, the cluster organization. The final report shall~~

- ~~Have an ecosystem map and description of the various water related technology clusters being proposed nationally. The report will also include a review of the local water technology cluster ecosystem map in Cincinnati/Dayton/ NKy/SE IN and if needed, a revised/updated map will be included in the report.~~
- ~~Identify the main strengths and weaknesses, threats, challenges, successes, and opportunities for EPA's collaboration with both the local regional water clusters and the national water technology cluster~~

~~organizations. Cultivate the lessons learned from these analyses into recommendations to EPA for effectively collaborating and networking with the various national water technology cluster organizations.~~

- ~~Provide EPA with best practices to effectively collaborate with both local and the national water technology cluster organizations using the concept of structured interactions between industry, research universities, and government.~~
- ~~Identify the important economic structures needed for successful and sustainable national water technology cluster organizations. Examples of these economic structures are infrastructures, human resources, linkages, regulatory policies, and access to technology and financial resources.~~
- ~~Identify metrics that can be used to prioritize activities, monitor and evaluate EPA's collaboration and networking role with local and the various national water technology cluster organizations.~~
- ~~Identify metrics that can be used to determine successful cluster organization outcomes, such as those being used by the US Small Business Administration.~~

Webinar

~~**Outreach**~~

a. Preliminary webinar dry run with USEPA, ORD Water Clusters Program.

- Webinar for EPA Clusters Program staff~~the ecosystem map~~ and ~~description of the various~~ water~~-related technology clusters being proposed nationally.~~
- ~~the best practices to implement for EPA to effectively collaborate with water technology cluster organizations.~~
- ~~the important economic structures needed for successful and sustainable national water technology cluster organizations.~~
- ~~the metrics that can be used to prioritize activities, monitor and evaluate EPA's collaboration and networking role with local and the various national water technology cluster organizations.~~

EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

WAM

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Alternate WAM

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-46

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	utero exposures to environment

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: Assessment Issues and Documents 1. Human Health As

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/30/2014 To 10/31/2015

Comments:
Literature search and analysis of available epidemiological data available for human health effects observed due to in utero exposures to environmental pollutants.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Andrew Hotchkiss (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-4164 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-46

TITLE: Literature search and analysis of available epidemiological data available for human health effects observed due to *in utero* exposures to environmental pollutants.

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: *CO Award thru 10/31/2015*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for conducting literature searches and subsequent analyses of human epidemiological studies that have observed health effects due to in utero exposure to environmental pollutants. The development of project will include the development of literature searches, systematic review (including risk of bias) evidence tables, identification of biomarkers of exposure and analyses of available NHANES data, derivation of points of departure (PODs) for select studies, characterization of the exposure distribution for women of reproductive age, evaluation of mechanistic data to provide insight into possible adverse outcome pathways (AOPs).

II. BACKGROUND

The importance of *in utero* exposures relative to environmental pollutants has resulted in numerous epidemiological studies characterizing the association between this critical time window of exposure and health effects resulting in later life. Based upon a brief literature search, epidemiological studies have characterized relationships between health effects and environmental pollutants including polybrominated diphenyl ether (Chen et al., 2013; Eskenazi, et al., 2013;), polyaromatic hydrocarbons (PAHs; Perera et al., 2012; 2009), arsenic (Graziano et al., 2014; Nadeau et al., 2014; Recio-Vega et al., 2014; Steinmaus et al., 2014), lead (Nye et al., 2014), methylmercury (Yorifuji, et al., 2014; Zeilmaker et al., 2011; Ryan, 2008), perfluorooctanoic acid (Chen et al., 2013;) and organochlorines (Vested et al., 2014; Eskenazi, et al., 2008). Of the many health effects associated with in utero exposures, developmental neurotoxicity appears to result from many environmental pollutants and this brief review indicates there may exist sufficient data for a number of environmental pollutants to focus on the decrements in IQ. However, based upon the initial literature search other endpoints may be selected to compare across environmental pollutants. Current human health assessments for many of the environmental pollutants identified here have yet to fully evaluate effects associated with in utero exposures. A focused effort on specific health effects (i.e., developmental neurotoxicity) across a group of compounds may provide insight and methodologies for future risk assessments. The Work Assignment Contracting Officer Representative (WA-COR) will provide technical direction as necessary.

In conducting the literature review, subsequent analyses, and documents characterizing the state of the science and analyses, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)

- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of analyses and documents characterizing the state of the science on health effects observed in human populations resulting from in utero exposures to environmental pollutants. Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA WA-COR.

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WA-COR and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WA-COR and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; and "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data.*"

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Literature search for identification of human epidemiological literature of health effects due to in utero exposure to environmental pollutants

The objective of this task is conduct complete literature searches to identify human epidemiological data that have observed human health effects in later life due to exposure to environmental pollutants in utero. Based upon the environmental pollutants there may be a range of available data. At this point, literature searches shall be inclusive of cancer and non-cancer effects associated with in utero exposures to environmental pollutants. The literature search strategy shall be documented and characterize the numerical results of the search. Based upon this literature search, data should be summarized in Hazard ID Summary tables (i.e., similar to tables developed for the inorganic arsenic human health risk assessment) for review and subsequent direction of this effort (i.e., selection of health effect endpoints to further characterize). When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

3.1 Literature Search and Hazard ID Summary Tables and Summary Report: The Contractor shall assist EPA in preparing revised versions of literature search and Hazard ID Summary tables based upon reviewer comments. A summary report will be drafted to characterize the available hazard information (human and primate studies only) for environmental pollutants identified in the literature search and to delineate a decision for the selection of health effect(s) / endpoint(s) for further analyses in this PWS. Comparability of data across relevant studies for the selected endpoints should be a key consideration in the selection of the health effect(s) / endpoint(s). Based upon the literature search results, PECO statements will be developed to guide subsequent analyses. Reviewers may include, but are not limited to, internal Agency and interagency participants.

Deliverables:
Literature search product and documentation
Hazard ID Summary tables
Summary report to document the available hazard information for identified chemicals, selection of health effects and develop PECO statement(s) for further analysis (based upon technical direction)

Task 4: Systematic Review and Derivation of Points of Departure (PODs)

The objective of this task is to conduct a systematic review of the available literature for the selected endpoint(s) to determine the most appropriate studies to derive a point of departure(s) that could be used for future derivation of toxicity values. This task will be highly dependent upon the available literature and selection of endpoint(s) / health effects to characterize across a group of environmental pollutants from Task 3. An initial estimate of potential studies on which a systematic review would be conducted may include on the order of 100 manuscripts. The systematic review will not be conducted on all endpoints / health effects identified in Task 3, but only endpoint(s) that are most comparable across studies for multiple environmental pollutants. The systematic review will be guided by the PECO statements developed in Task 3 and be limited in scope. The protocol for the systematic review (including risk of bias) will be documented prior to evaluating studies. Based upon the results from the systematic review, the best available studies for each pollutant will be utilized for derivation of potential PODs.

Specific requirements of this task:

4.1 Systematic Review and Dose-Response Analyses

Deliverables:
Systematic Review Protocol
Risk of bias evaluations
Summary report of systematic review of selected studies
POD derivations
Summary report of POD derivations

Task 5: Efforts related Exposure Characterization

The objective of this task is to characterize exposure to the identified environmental pollutants using existing public databases. The National Health and Nutrition Examination Survey (NHANES) routinely collects biomarkers of exposure (e.g., blood and urine levels) for well- known environmental pollutants. For the environmental pollutants identified in Task 3, for which there is sufficient epidemiological data to suggest a potential human health hazards, NHANES and other publicly available databases will be searched to identify biomarkers of exposure. Based upon the available data the goal of this task will be to characterize the distribution of exposure to women of reproductive age, however this task will be limited by the available data. The approach and boundaries for identification, data retrieval, and exposure characterization will be dependent upon the environmental pollutants identified in Task 3. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

5.1 Exposure Characterization: The Contractor shall assist EPA in drafting documents to characterize the exposure profile within United States populations and the retrieval of exposure information from publicly available databases

Deliverables:
General exposure profiles for US populations for each environmental pollutant (estimated 10)
Exposure characterization based upon exposure biomarkers from publicly available databases for women of reproductive age

Task 6: Efforts related to development of Adverse Outcome Pathways (AOPs)

The objective of this task is to assist EPA in evaluating the available mechanistic information for the endpoint(s) selected in Task 3. Based upon the endpoint selected in Task 3, the contractor shall conduct a complete literature search for mechanistic information that may support the development of AOPs for the selected endpoint(s). The available information should be arranged by components of AOP analysis (i.e., molecular initiating event, etc.). Based upon the endpoint(s) selected a review of available proposed AOPs or modes of action (MOA) should also be evaluated. Based upon the available information the WA-COR will provide technical direction as to the feasibility of developing an AOP for the selected endpoints.

Specific requirements of this task:

6.1 AOP Evaluation and Analyses: The contractor shall develop a summary report characterizing the available mechanistic information available for development of AOPs for the selected endpoint. Further analyses may be required to document and develop an AOP analyses.

Deliverable:
Summary report of available mechanistic information
Review of available AOP hypotheses
Development of a proposed AOP(s)

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award
Task 3. Literature Search for Epi Literature from In Utero Exposures	
Task 3.1 – Literature Search and Hazard ID	
• Literature Search Product and Documentation	3 weeks from completion of Task 2
• Hazard ID Summary Tables	5 weeks from completion of Task 2
• Summary Report for Hazard ID	10 weeks from completion of Task 2
Task 4. Systematic Review and POD Derivation	
Task 4.1 – Systematic Review and Dose-Response Analyses	
• Systematic Review Protocol	3 weeks from completion of Task 3
• Risk of Bias Evaluations	5 weeks from completion of Task 3
• Summary Report Sys Rev/ Selected Studies	8 weeks from completion of Task 3
• POD Derivations	12 weeks from completion of Task 3
• Summary Report PODs	14 weeks from completion of Task 3
Task 5. Efforts Related to Exposure Characterization	
Task 5.1 – Exposure Characterization	
• General Exposure Profiles for Selected Pollutants	3 weeks from completion of Task 3
• Exposure Characterization Publicly Available Biomarker Data	8 weeks from completion of Task 3

Task 6. Efforts related to AOPs	
Task 6.1 – AOP Evaluation and Analyses	
• Summary Report of Available Mechanistic Info for Selected Endpoint(s)	3 weeks from completion of Task 5
• Review of Available AOPs	6 weeks from completion of Task 5
• Development of Proposed AOPs	10 weeks from completion of Task 5

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WA-COR or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WA-COR at the initiation of the work assignment, and shall provide a bi-weekly update to the WA-COR by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Contracting Officer Representative (WA-CORs):

Andrew Hotchkiss, PhD
919-541-4164
Hotchkiss.Andrew@epamail.epa.gov

John Cowden, PhD (Alternate)
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Cowden.John@epamail.epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-46

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	utero exposures to environment

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: Assessment Issues and Documents 1. Human Health As

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/30/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

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SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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4										
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Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
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This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Andrew Hotchkiss (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-4164 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-46 Amendment 1

TITLE: Literature search and analysis of available epidemiological data available for human health effects observed due to *in utero* exposures to environmental pollutants.

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: *CO Award thru 10/31/2015*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for conducting literature searches and subsequent analyses of human epidemiological studies that have observed health effects due to in utero exposure to environmental pollutants. The development of project will include the development of literature searches, systematic review (including risk of bias) evidence tables, identification of biomarkers of exposure and analyses of available NHANES data, derivation of points of departure (PODs) for select studies, characterization of the exposure distribution for women of reproductive age, evaluation of mechanistic data to provide insight into possible adverse outcome pathways (AOPs).

II. BACKGROUND

The importance of *in utero* exposures relative to environmental pollutants has resulted in numerous epidemiological studies characterizing the association between this critical time window of exposure and health effects resulting in later life. Based upon a brief literature search, epidemiological studies have characterized relationships between health effects and environmental pollutants including polybrominated diphenyl ether (Chen et al., 2013; Eskenazi, et al., 2013;), polyaromatic hydrocarbons (PAHs; Perera et al., 2012; 2009), arsenic (Graziano et al., 2014; Nadeau et al., 2014; Recio-Vega et al., 2014; Steinmaus et al., 2014), lead (Nye et al., 2014), methylmercury (Yorifuji, et al., 2014; Zeilmaker et al., 2011; Ryan, 2008), perfluorooctanoic acid (Chen et al., 2013;) and organochlorines (Vested et al., 2014; Eskenazi, et al., 2008). Of the many health effects associated with in utero exposures, developmental neurotoxicity appears to result from many environmental pollutants and this brief review indicates there may exist sufficient data for a number of environmental pollutants to focus on the decrements in IQ. However, based upon the initial literature search other endpoints may be selected to compare across environmental pollutants. Current human health assessments for many of the environmental pollutants identified here have yet to fully evaluate effects associated with in utero exposures. A focused effort on specific health effects (i.e., developmental neurotoxicity) across a group of compounds may provide insight and methodologies for future risk assessments. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In conducting the literature review, subsequent analyses, and documents characterizing the state of the science and analyses, the Contractor shall follow, as applicable, the following EPA guidance documents:

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- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
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- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of analyses and documents characterizing the state of the science on health effects observed in human populations resulting from in utero exposures to environmental pollutants. Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance*

Project Plans (QA/R-5)"; and "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data*."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Literature search for identification of human epidemiological literature of health effects due to in utero exposure to environmental pollutants

The objective of this task is conduct complete literature searches to identify human epidemiological data that have observed human health effects in later life due to exposure to environmental pollutants in utero. Based upon the environmental pollutants there may be a range of available data. At this point, literature searches shall be inclusive of cancer and non-cancer effects associated with in utero exposures to environmental pollutants. The literature search strategy shall be documented and characterize the numerical results of the search. Based upon this literature search, data should be summarized in Hazard ID Summary tables (i.e., similar to tables developed for the inorganic arsenic human health risk assessment) for review and subsequent direction of this effort (i.e., selection of health effect endpoints to further characterize). When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

3.1 Literature Search and Hazard ID Summary Tables and Summary Report: The Contractor shall assist EPA in preparing revised versions of literature search and Hazard ID Summary tables based upon reviewer comments. A summary report will be drafted to characterize the available hazard information (human and) for environmental pollutants identified in the literature search and to delineate a decision for the selection of health effect(s) / endpoint(s) for further analyses in this PWS. Comparability of data across relevant studies for the selected endpoints should be a key consideration in the selection of the health effect(s) / endpoint(s). Based upon the literature search results, PECO statements will be developed to guide subsequent analyses. Reviewers may include, but are not limited to, internal Agency and interagency participants.

Deliverables:
Literature search product and documentation
Hazard ID Summary tables
Summary report to document the available hazard information for identified chemicals, selection of health effects and develop PECO statement(s) for further analysis (based upon technical direction)

Task 4: Systematic Review and Derivation of Points of Departure (PODs)

The objective of this task is to conduct a systematic review of the available literature for the selected endpoint(s) to determine the most appropriate studies to derive a point of departure(s) that could be used for future derivation of toxicity values. This task will be highly dependent upon the available literature and selection of endpoint(s) / health effects to characterize across a group of environmental pollutants from Task 3.

The systematic review will be conducted on endpoints / health effects identified in Task 3, but only endpoint(s)

.

The systematic review will be guided by the PECO statements developed in Task 3 and be limited in scope. The protocol for the systematic review (including risk of bias) will be documented prior to evaluating studies.

Based upon the results from the systematic review, the best available studies for each pollutant will be utilized for derivation of potential PODs.

Specific requirements of this task:

4.1 Systematic Review and Dose-Response Analyses

Deliverables:
Systematic Review Protocol
Risk of bias evaluations
Summary report of systematic review of selected studies
POD derivations
Summary report of POD derivations

Task 5: Efforts related Exposure Characterization

The objective of this task is to characterize exposure to the identified environmental pollutants using existing public databases. The National Health and Nutrition Examination Survey (NHANES) routinely collects biomarkers of exposure (e.g., blood and urine levels) for well- known environmental pollutants. For the environmental pollutants identified in Task 3, for which there is sufficient epidemiological data to suggest a potential human health hazards, NHANES and other publicly available databases will be searched to identify biomarkers of exposure. Based upon the available data the goal of this task will be to characterize the distribution of exposure to women of reproductive age, however this task will be limited by the available data. The approach and boundaries for identification, data retrieval, and exposure characterization will be dependent upon the environmental pollutants identified in Task 3. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

5.1 Exposure Characterization: The Contractor shall assist EPA in drafting documents to characterize the exposure profile within United States populations and the retrieval of exposure information from publicly available databases

Deliverables:
General exposure profiles for US populations for each environmental pollutant (estimated 10)
Exposure characterization based upon exposure biomarkers from publicly available databases for women of reproductive age

Task 6: Efforts related to development of Adverse Outcome Pathways (AOPs)

The objective of this task is to assist EPA in evaluating the available mechanistic information for the endpoint(s) selected in Task 3. Based upon the endpoint selected in Task 3, the contractor shall conduct a complete literature search for mechanistic information that may support the development of AOPs for the selected endpoint(s). The available information should be arranged by components of AOP analysis (i.e., molecular initiating event, etc.). Based upon the endpoint(s) selected a review of available proposed AOPs or modes of action (MOA) should also be evaluated. Based upon the available information the WAM will provide technical direction as to the feasibility of developing an AOP for the selected endpoints.

Specific requirements of this task:

6.1 AOP Evaluation and Analyses: The contractor shall develop a summary report characterizing the available mechanistic information available for development of AOPs for the selected endpoint. Further analyses may be required to document and develop an AOP analyses.

Deliverable:
Summary report of available mechanistic information
Review of available AOP hypotheses
Development of a proposed AOP(s)

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IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3. Literature Search for Epi Literature from In Utero Exposures	
Task 3.1 – Literature Search and Hazard ID	
• Literature Search Product and Documentation	3 weeks from completion of Task 2
• Hazard ID Summary Tables	5 weeks from completion of Task 2
• Summary Report for Hazard ID	10 weeks from completion of Task 2
Task 4. Systematic Review and POD Derivation	
Task 4.1 – Systematic Review and Dose-Response Analyses	
• Systematic Review Protocol	3 weeks from completion of Task 3
• Risk of Bias Evaluations	5 weeks from completion of Task 3
• Summary Report Sys Rev/ Selected Studies	8 weeks from completion of Task 3
• POD Derivations	12 weeks from completion of Task 3
• Summary Report PODs	14 weeks from completion of Task 3
Task 5. Efforts Related to Exposure Characterization	
Task 5.1 – Exposure Characterization	
• General Exposure Profiles for Selected Pollutants	3 weeks from completion of Task 3
• Exposure Characterization Publicly Available Biomarker Data	8 weeks from completion of Task 3
Task 6. Efforts related to AOPs	
Task 6.1 – AOP Evaluation and Analyses	
• Summary Report of Available Mechanistic Info for Selected Endpoint(s)	3 weeks from completion of Task 5
• Review of Available AOPs	6 weeks from completion of Task 5
• Development of Proposed AOPs	10 weeks from completion of Task 5

Note: All days are calendar days.

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VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Managers (WAMs):

Andrew Hotchkiss, PhD		, PhD
919-541-4164	919-541-	
Hotchkiss.Andrew@epamail.epa.gov		@epamail.epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-46

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Utro Exposure to Environment

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A.Assessment Issues and Documents

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/30/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$134,729.00	1,469
Total:	$134,729.00	1,469

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 03/31/2015	$134,729.00	1,469
Cumulative Approved:	$134,729.00	1,469

Work Assignment Manager Name: Andrew Hotchkiss (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-4164 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-47

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	SUPPORT FOR NCCT
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B, D, E, F

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/30/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Richard Judson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3085 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-47

TITLE: TECHNICAL SUPPORT FOR NCCT PROFESSIONAL SERVICES

Specify Section & Paragraph SOW: Please select from the following:

B. Risk Assessment Methods Research and Development
g. Development and evaluation of mathematical and statistical methods to address human health or environmental risks. Expert, non-routine statistical analysis of relevant data. Expert development and evaluation of mathematical models to represent biological or environmental systems and processes.
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support
F. Information Management

PERIOD OF PERFORMANCE: *CO award – October 31- 2015*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Computational Toxicology (NCCT), Office of Research and Development (ORD).

II. BACKGROUND

The National Center for Computational Toxicology (NCCT) of the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (ORD) is developing methods and models for screening large numbers of chemicals for biological activity and exposure. The ultimate aim of this project is to use new technologies (including high-throughput in vitro screening methods, high-throughput toxicokinetics methods, alternative species, and predictive exposure models) to generate data that can be used to prioritize chemicals for further evaluation. To do so, EPA launched the ToxCast program. ToxCast has evaluated over 2,000 chemicals from a broad range of sources including: industrial and consumer products, food additives, and potentially "green" chemicals that could be safer alternatives to existing chemicals. Chemicals were evaluated in over 700 high-throughput screening assays that include both cell-based and biochemical assays. To date, this effort has generated over 2 million data points.

A major tool supporting this effort is the ToxCast data analysis pipeline, which is organized as follows. First, all raw source data files are converted into a single raw data format [level 0]. The next three steps consist of performing automated chemical/assay mapping and concentration/replicate indexing [level 1], performing raw data correction (e.g., log conversions, plate level corrections, concentration corrections) [level 2], and assay specific data normalization to supply highly consistent data formats for the curve fitting process [level 3]. The next step involves modeling the data with a constant model, non-linear Hill model, and a gain-loss model (gain of signal Hill model multiplied by a loss of signal Hill model) to evaluate the concentration responsiveness of each sample-assay combination, as well as to derive estimates of potency and efficacy [level 4]. The fifth step includes automated activity calls based on the quality of the model fits (e.g., AIC [Akaike Information Criteria]

of Hill model vs. AIC of constant model) as well as statistically- or biologically- derived response cutoffs (top of Hill model or gain-loss model vs. 10 MAD (median absolute deviation) around the baseline, or 20%, whichever is greater) [level 5]. The final automated step in the process involves assigning "activity qualifier flags" to specific sample-assay combinations that have systematic data confounders detected (e.g., fluorescence, edge effects, contaminating luminescent "flare" from neighboring wells) or were deemed to be low confidence/borderline positive activity calls [level 6]. At each step in the process, the ToxCast data analysis pipeline has data quality metrics that quantify assay performance and quality. All information (raw and processed data, flags, model parameters, etc.) are stored in a relation database called InvitroDB. Final results are uploaded into the ToxCast dashboard database which serves as the primary portal for publication and data release.

Critical to regulatory use, as well as public acceptance, of the data is that the analysis pipeline is viewed as scientifically accurate. In order to provide evidence of accuracy, an independent review of the results of the automated process is needed. The proposed project will take advantage of scientific expertise outside the Agency to provide an independent audit of the overall quality of the data and output from the data analysis pipeline in ToxCast.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 5 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of statistics and in vitro screening.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager.
The QAPP shall be submitted simultaneously with the Work Plan for approval.

Specific Tasks

The Contractor will be provided with the following information:

- The NCCT Internal document entitled "ToxCast Data Analysis Pipeline User Guide".
- The NCCT Internal document entitled "ToxCast Chemical User Guide"
- A set of PDF files in which each page contain a graphical representation of the processed data, curve fits, a hit call, activity qualifier flags, and a table of statistical information. These will be provided for a subset of the 1,000,000+ concentration-response curves available from InvitroDB. The subset will include chemical-assay pairs that are :
    - Clearly negative. Approximately 75% of the total chemical-assay pairs have negative automated hit calls. This includes concentration-response data with no significant curve fits, data that do not exceed response cut-offs, etc. A random selection of 2.5% of these will be provided to the Contractor.

- Positives. Approximately 25% of all chemical-assay pairs have positive automated hit calls. These curves fall into two categories:
    - There are approximately 50k concentration-response curves that are clear positives. These are curves that are easily identified visually as being a hit. This includes curves with statistically significant curve fits, data points that exceed response cutoffs, high maximum responses, few or no outlier data points, etc.
    - Concentration-response curves that demonstrate a response pattern that is associated with a positive hit, but also have activity qualifier flags. These include flags for auto-fluorescence, contaminating luminescent "flare", edge effects, etc. There are about 150k curves of this type. Required metadata to check on these calls will also be provided.

The Contractor shall accomplish the following tasks and shall complete them according to the estimated time schedule given below.

Task 3. Training on the ToxCast Data Analysis Pipeline

The contractor shall have access to all required technical materials in regards to the data pipeline. Training sessions will be provided by EPA/NCCT staff as needed to ensure that the Contractor understands the data analysis pipeline adequate enough to review the outputs from the data analyses pipeline. This is specialized training specific to EPA/NCCT Systems and is not available on the open market.

Task 4. Development of data review strategy.

The Contractor shall develop a data review strategy, which will be finalized through an iterative set of discussions with the Agency. This step will ensure that the process will provide the necessary and needed outputs. The following criteria shall be used to develop this strategy. The review strategy shall include

1. Review hits and non-hits and confirm automated hit calls with a yes or no.
2. Review curve-fits and estimated potency and efficacy values to ensure that they are consistent with the data.
3. Review automated activity qualifier flags and confirm their accuracy.

The Contractor shall meet with Agency staff per the deliverables schedule below, present the review strategy, and develop a final version that is acceptable to the Agency, through iterative consultations. The final Agency approved review strategy will be used by the Contractor to review the curve-fits and hit-calls as described in Task 5.

Task 5. Expert review of automated data analysis outputs.

The following number of chemical-assay outputs shall be reviewed [Note that these are estimates, and that final percentages will be determined through the data review strategy development.]:

1. Negative hit calls – a random selection of 1% of the available chemical-assay pairs (a total of ~7500 concentration-response curves).

2. Positive hit calls with no data qualifier flags – a random selection of 10% of the chemical-assay pairs (a total of ~5000 concentration-response curves).

3. Positive hit calls with some data qualifier flags – a random selection of 10% of the chemical-assay pairs (a total of ~5000 concentration-response curves).

The contractor shall review the curve-fits, potency and efficacy estimates, hit-calls, and activity qualifier flags for accuracy. For each chemical-assay pair, the contractor shall provide an agreement with the analysis or

a disagreement with the analysis as well as succinct reasons for any disagreement (e.g., inappropriate model fit, spurious/outlier point driven activity call, suspiciously high efficacy (e.g., 1000% of positive control), overly noisy baseline, etc.)

Task 6. Summary Report and Recommendations

The Contractor shall provide a summary report that contains a record of all observations for all reviewed chemical-assay outputs and overall summary statistics for each category of activity calls.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents,).

V. DELIVERABLES AND SCHEDULE

The Contractor shall initiate these meetings and provide products in the form of a report consisting of summary statistics of the review and overall comments; plus detailed spreadsheets with all chemical-assay pair results.

Task 1. Initial Review Strategy	Meeting 5 days after award of Work Assignment, documentation of meeting due 5 days after meeting
Task 2. Staffing Plan, and QAPP	20 days after award
Task 3. Final Review Plan, Incorporating EPA Comments	Documents due 5 days after receipt of EPA Comments
Task 4. Review Selection of "negative" results	Draft report due 10 days after final plan approval
Task 5. Review Selection of "positive" Calls	Draft report due 10 days after final plan approval
Task 6. Final Report	Final Report due 30 days after final plan approval

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

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VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

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Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

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The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):
Richard Judson – WAM
Sandra Roberts – Alternate WAM

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-47

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	TECHNICAL SUPPORT FOR NCCT PRO

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/30/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Richard Judson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3085 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-47 Amend 1

TITLE: TECHNICAL SUPPORT FOR NCCT PROFESSIONAL SERVICES

PERIOD OF PERFORMANCE: CO approval through 10/31/2015

I. PURPOSE

The purpose of this modification is to provide an independent review of the ToxCast database computer code for consistency and accuracy. This work falls under Heading III - Specific Areas of Work, Section C (Risk Assessment Data Bases and Computer Tools, paragraph 1) and Section F (Information Management). Also relevant to this modification is Heading IV- Product Quality, Section B (Quality Assurance/Quality Control Requirements) as it relates to ensuring that data generated are "of the type and quality needed and expected for their intended use."

II. BACKGROUND

The National Center for Computational Toxicology (NCCT) of the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (ORD) is developing methods and models for screening large numbers of chemicals for biological activity and exposure. A major tool supporting this effort is the ToxCast data analysis pipeline. All information (raw and processed data, flags, model parameters, etc.) are stored in a relational database called InvitroDB. Final results are made available through the ToxCast dashboard which serves as the primary portal for publication and data release.

Critical to regulatory use as well as public acceptance of the data is that the analysis pipeline is viewed as scientifically accurate. In order to provide evidence of accuracy, an independent review of the results of the automated process is needed. The proposed project will take advantage of scientific expertise outside the Agency to provide an independent audit of the overall quality of the code contained in ToxCast.

III. STATEMENT OF WORK

Task: Review of ToxCast Database Computer Code

Step 1: The contractor will follow the provided instructions to download and install invitrodb_v1 and the tcpl R package locally, verifying that the documentation for this process is complete. This installation will require the use of MySQL and R on Windows 7, OS/X and Linux. Evaluators are expected to be proficient with installation and configuration of MySQL and R. In

all cases, 64-bit versions will be used. Because the R-MySQL package can be problematic to install, brief instructions will be included.

Step 2: The contractor will perform the pipeline processing on one assay endpoint from each of the 7 data vendors, selected randomly. Instructions, including example code will be provided.

Step 3: Comment on level and clarity of documentation in the user manual (R package vignette), and function documentation provided with the tcpl R package.

Requirements for reviewer(s):

1. Reasonable experience with R programming and documentation, including R package structure and installing R packages from source in the Windows environment
2. Reasonable experience utilizing MySQL relational databases, including database installation (from a zip file) and database administration (updating permissions, changing database settings, etc.)

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-47

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	TECHNICAL SUPPORT FOR NCCT PRO

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/30/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$51,569.00	493
Total:	$51,569.00	493

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 03/30/2015	$51,569.00	493
Cumulative Approved:	$51,569.00	493

Work Assignment Manager Name: Richard Judson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3085 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-48

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	HERO-DRAGON
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: F. Information Management

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 02/26/2015 To 10/31/2015

Comments:
NCEA-HERO-DRAGON Interface & NCEA-HERO Support

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Connie Meacham (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3908 FAX Number: 919-541-5078
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK Statement
Contract EP-C-14-001
Work Assignment 1-48

Title: **NCEA-HERO-DRAGON Interface & NCEA-HERO Support**

SOW Section & Paragraph: F. Information Management

Period of Performance: CO Approval to October 31, 2015

I. Purpose

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) in the Office of Research and Development (ORD), in the National Center for Environmental Assessment (NCEA). Specifically, to provide services to support the NCEA Health and Environmental Research Online (HERO) database system, which is a tool used in developing Human Health Science Assessments and other NCEA documents.

II. Background

HERO is U.S. EPA National Center for Environmental Assessment application database system containing bibliographic references used in assessment development process. HERO currently includes nearly 2 million bibliographic references; ~80% are articles from peer-reviewed scientific research journals. There are several modules within the HERO database system tool (e.g., LitSearch, Literature Import tools, LitBrowser tools [includes Project Pages, Tagging, LitFlow diagrams, Generation of Project-specific EndNote Libraries, and LitCiter], LitScreener, LitExtractor, ProjectTracker/Comment Tracker, etc.).

III. Statement of Work

A. Objective

The contractor shall perform various tasks for NCEA in support of the various projects and modules in HERO. The WAM, Connie Meacham, will give technical direction on the support tasks.

The tasks involve:

- Developing a HERO-DRAGON interface (web services API), and other methods of electronic transfer of information collected in the NCEA/ICF DRAGON tool (i.e., literature screening data, modeling data, extracted data, and formatted DRAGON output) into HERO,
- Data cleaning and quality control of information on the HERO Project Pages and LitFlow Diagrams associated with various programs within NCEA (such as ISAs, IRIS Toxicological Reviews, PPRTVs, and Other high-profile projects). Developing user documentation on HERO modules. Data entry into Project Tracker/Comment Tracker in the HERO Database System.

The WAM will provide prompt feedback to the contractor on the acceptability and performance of the tasks.

B. Specific Requirements

Task 1: Develop a HERO-DRAGON interface (web services API), and other methods of electronic transfer of modeling data, screening data, and extracted data from DRAGON into HERO.

Skills needed: Understanding of web services API (Application Programming Interface), Microsoft Office (MS) Access Databases, MS Excel Spreadsheets, Word Tables, NoSQL databases, and

DRAGON processes (literature screening, data extraction / fact extraction) and DRAGON queries and output formats.

Task 2: Data cleaning and quality control of information on the HERO Project Pages and LitFlow diagrams; developing user documentation (and updating webpage information); and data entry into Project Tracker/Comment Tracker.

EPA will provide the EPA Portal accounts and HERO tools and permissions as necessary.

Skills needed: Attention to detail, understanding of bibliographic reference data, a thorough understanding of HERO applications and EPA user environment, technical writing skills, an understanding of the assessment development process.

Task 2 consists of 3 parts:

Part 2A: Data Cleaning

The WAM will assign the projects for which the bibliographic references shall be checked for completeness and accuracy. Each project shall be checked for appropriateness of the "tag tree" associated with the project on the Project Page and the LitFlow diagram. This "tag tree" checking may involve the EPA chemical (project expert) manager of the project as well as the WAM. The contractors shall enter corrections directly in the HERO database using the HERO web interface.

Part 2B: User Documentation and Update of Information on the HERO Webpages.

The contractor shall create user documentation for the HERO modules that will be available soon, and update the current documentation for the current HERO modules. The information on the public view and the Agency view of HERO shall be updated.

Part 2C: Data entry into Project Tracker/Comment Tracker.

The contractor shall enter project tracking data for specific NCEA projects (the WAM will assign the projects to the contractor). The data will include Steps in the project and Activities that will take place over the lifecycle of the project. For specified projects, comments about the project shall be attached to the Project Tracker/Comment Tracker (such as public comments, comments from peer reviewers [SAB, NAS, Interagency, etc.], summaries of comments, linked lists of Docket comments, etc.).

IV. Deliverables

The contractor shall use the NCEA HERO online tracking system (JIRA) to receive specific tickets, which will include details of the tasks, deliverables and schedule. All deliverables will be electronic.

The NCEA HERO team maintains a work request system using a JIRA installation running on an ORD server. All technical directions will be given with references to ticket numbers in this system. Estimates of hours per ticket assignment and expected deliverable deadlines will be recorded in this system and shared with the Contractor. The Contractor shall be expected to provide communications through this tool.

If the JIRA system is down or not functional for any reason, email will be used to communicate with the contractor. The contractor shall create a new JIRA ticket and copy and paste the email string into the new JIRA ticket as soon as possible, after the system is back online.

V. Notice Regarding Guidance Provided under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM. Technical direction can only come from a WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA W AM at the initiation of the work assignment. The contractor shall use the NCEA HERO electronic tracking system (JIRA) to document all tasks.

Periodic meetings (generally once every week, or once every 2 weeks if there are scheduling conflicts) between the EPA WAM and contractor staff shall be necessary to discuss questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or webinar. The contractor shall document these meetings and submit copies of this documentation to the EPA WAM.

Travel: No Travel is expected to occur during the course of this work assignment.

Green Meetings: No in-person meetings are expected to occur during the course of this work assignment.

VII. EPA Contact Information

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO (Melissa Revely-Wilson; revely-wilson.melissa@epa.gov). This does not include technical direction in the NCEA HERO electronic tracking system (JIRA).

Work Assignment Manager (WAM)

Connie A. Meacham, M.S. (Biologist)
HERO Project Lead
U.S. EPA, NCEA-RTP
109 TW Alexander Drive, Mail Drop B243-01
Research Triangle Park, NC 27711
Telephone: (919) 541- 3908
Cell: (919) 369-8600
meacham.connie@epa.gov

Packages/Courier Address:
Connie Meacham
U.S. EPA MD B243-01
4930 Old Page Road
Durham, NC 27703

Alternative Work Assignment Manager (Alt-WAM)

Ryan Jones, M.S. (Information Specialist)
HERO Technical Lead
U.S. EPA, NCEA-RTP
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Fax: (919) 541- 5078
jones.ryan@epa.gov

Packages/Courier Address:
Ryan Jones
U.S. EPA MD B243-01
4930 Old Page Road
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-48

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	HERO-DRAGON Interface
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: F. Information Management

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 02/26/2015 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Connie Meacham (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3908 FAX Number: 919-541-5078
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

Revised PERFORMANCE WORK Statement
Contract EP-C-14-001
Work Assignment no. 1-48

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Title: **NCEA-HERO-DRAGON Interface & NCEA-HERO Support**

SOW Section & Paragraph: F. Information Management

Period of Performance: CO Approval to October 31, 2015

I. Purpose

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) in the Office of Research and Development (ORD), in the National Center for Environmental Assessment (NCEA). Specifically, to provide services to support the NCEA Health and Environmental Research Online (HERO) database system, which is a tool used in developing Human Health Science Assessments and other NCEA documents.

II. Background

HERO is U.S. EPA National Center for Environmental Assessment application database system containing bibliographic references used in assessment development process. HERO currently includes nearly 2 million bibliographic references; ~80% are articles from peer-reviewed scientific research journals. There are several modules within the HERO database system tool (e.g., LitSearch, Literature Import tools, LitBrowser tools [includes Project Pages, Tagging, LitFlow diagrams, Generation of Project-specific EndNote Libraries, and LitCiter], LitScreener, LitExtractor, ProjectTracker/Comment Tracker, etc.).

III. Statement of Work

A. Objective

The contractor shall perform various tasks for NCEA in support of the various projects and modules in HERO. The WAM, Connie Meacham, will give technical direction on the support tasks.

The tasks involve:

- Developing a HERO-DRAGON interface (web services API), and other methods of electronic transfer of information collected in the NCEA/ICF DRAGON tool (i.e., literature screening data, modeling data, extracted data, and formatted DRAGON output) into HERO.~~,~~
- Data cleaning and quality control of information on at least 20 different ~~the~~ HERO Project Pages and any associated LitFlow Diagrams associated with various programs within NCEA (such as ISAs, IRIS Toxicological Reviews, PPRTVs, and Other high-profile projects). Developing extensive and 1-page summary user documentation on at least ten HERO modules and processes. ~~Data entry into Project Tracker/Comment Tracker in the HERO Database System.~~

The WAM will provide prompt feedback to the contractor on the acceptability and performance of the tasks.

B. Specific Requirements

Task 1: Revise the Work Plan to reflect the changes in Level of Effort in this revised PWS and the WA Amendment.

Task 2~~1~~: Develop a HERO-DRAGON interface (web services API), and other methods of electronic transfer of modeling data, screening data, and extracted data from DRAGON into HERO. Alternate

methods of data sharing, such as Current Master DRAGON MS Access Databases form each Discipline (Epidemiology, Animal Toxicology, In Vitro Toxicology, etc.), which include the current Fields and Values Tables in the MS Access databases, can be shared with the EPA WAM as soon as possible, to help prepare the data structure on the HERO database server (preparation for receiving the DRAGON-extracted data via the API). Additional methods of phased electronic data transfer will be necessary to move this task forward if the API is delayed past June 30, 2015.

Skills needed: Understanding of web services API (Application Programming Interface), Microsoft Office (MS) Access Databases, MS Excel Spreadsheets, Word Tables, MySQL databases, NoSQL databases, and DRAGON processes (literature screening, data extraction / fact extraction) and DRAGON queries and output formats.

Task 32: Data cleaning and quality control of information on various~~the~~ HERO Project Pages and LitFlow diagrams; developing user documentation (and updating webpage information); and data entry into Project Tracker/Comment Tracker.

EPA will provide the EPA Portal accounts and HERO tools and permissions as necessary.

Skills needed: Attention to detail, understanding of bibliographic reference data, a thorough understanding of HERO applications and EPA user environment, technical writing skills, an understanding of the assessment development process.

Task 32 consists of 2~~3~~ parts:

Part 32A: Data Cleaning

The WAM will assign the projects for which the bibliographic references shall be checked for completeness and accuracy. Each project shall be checked for appropriateness of the "tag tree" associated with the project on the Project Page and the LitFlow diagram. This "tag tree" checking may involve the EPA chemical (project expert) manager of the project as well as the WAM. The contractors shall enter corrections directly in the HERO database using the HERO web interface.

Part 32B: User Documentation and Update of Information on the HERO Webpages.

The contractor shall create user documentation for the HERO modules that will be available soon, and update the current documentation for the current HERO modules. The information on the public view and the Agency view of HERO shall be updated.

~~**Part 2C:** Data entry into Project Tracker/Comment Tracker.~~

~~The contractor shall enter project tracking data for specific NCEA projects (the WAM will assign the projects to the contractor). The data will include Steps in the project and Activities that will take place over the lifecycle of the project. For specified projects, comments about the project shall be attached to the Project Tracker/Comment Tracker (such as public comments, comments from peer reviewers [SAB, NAS, Interagency, etc.], summaries of comments, linked lists of Docket comments, etc.).~~

IV. Deliverables

The contractor shall use the NCEA HERO online tracking system (JIRA) to receive specific tickets, which will include details of the tasks, deliverables and schedule. All deliverables will be electronic.

The NCEA HERO team maintains a work request system using a JIRA installation running on an ORD server. All technical directions will be given with references to ticket numbers in this system. Estimates of hours per ticket assignment and expected deliverable deadlines will be recorded in this system and shared with the Contractor. The Contractor shall be expected to provide communications through this tool.

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V. Notice Regarding Guidance Provided under this Project

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(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA W AM at the initiation of the work assignment. The contractor shall use the NCEA HERO electronic tracking system (JIRA) to document all tasks.

Periodic meetings (generally once every week, or once every 2 weeks if there are scheduling conflicts) between the EPA WAM and contractor staff shall be necessary to discuss questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or webinar. The contractor shall document these meetings and submit copies of this documentation to the EPA WAM.

Travel: No Travel is expected to occur during the course of this work assignment.

Green Meetings: No in-person meetings are expected to occur during the course of this work assignment.

VII. EPA Contact Information

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO (Melissa Revely-Wilson; revely-wilson.melissa@epa.gov). This does not include technical direction in the NCEA HERO electronic tracking system (JIRA).

Work Assignment Manager (WAM)

Connie A. Meacham, M.S. (Biologist)
HERO Project Lead
U.S. EPA, NCEA-RTP
109 TW Alexander Drive, Mail Drop B243-01
Research Triangle Park, NC 27711
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Connie Meacham
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Alternative Work Assignment Manager (Alt-WAM)

Ryan Jones, M.S. (Information Specialist)
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-48

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	HERO - Dragon
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	F. Information Management

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 02/26/2015 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$341,404.00	4,547
Total:	$341,404.00	4,547

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 06/04/2015	$341,404.00	4,547
Cumulative Approved:	$341,404.00	4,547

Work Assignment Manager Name: Connie Meacham (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3908 FAX Number: 919-541-5078
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-49

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Ethylene Oxide
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A.1,2,4 and B.1,2,5

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/06/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-49

TITLE: Ethylene Oxide - Epidemiology Modeling and Exposure Characterization

---

Principal Section & Paragraph of SOW: A.1,2,4 and B.1,2,5

PERIOD OF PERFORMANCE: Approval – October 31, 2015

I. PURPOSE

The purpose of the work assignment is to provide services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of a carcinogenicity assessment for Ethylene Oxide. Specifically, this work assignment will provide exposure-response modeling using NIOSH cohort study data, and, separately, characterizations of exposure levels estimated for jobs and locations pertinent to the cohort study.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

These Tasks are undertaken to respond to recommendations of the EPA Science Advisory Board (SAB) after its review (November 18-20, 2014) of the Ethylene Oxide Assessment. All work must be completed before December 31, 2015. This work will begin based on information from the SAB review in November 2014 and the draft written review due in February 2015. A final review may be available around June or July, 2015. This PWS ends on October 31, 2015, but could be continued into option year 2 if necessary. Undertaking these Tasks will require experience with exposure-response modeling of cohort study data, in particular with two-piece spline models, as well as familiarity with and access to the NIOSH cohort study data, including the incidence study data, and the NIOSH exposure assessment. Further materials related to the Ethylene Oxide Assessment will be provided by EPA.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP
Due Date: 20 days after issuance of this Performance Work Statement (PWS).

Task 2. Exposure-Response Modeling of NIOSH Cohort Study Data

Exposure-response modeling was conducted for the Ethylene Oxide ("EtO") assessment prior to SAB review. The SAB requested further analyses. These include (other analyses might be required, depending on further communication with SAB):

a. additional exposure-response modeling of the NIOSH cohort study data, including but not limited to:
    i. sensitivity analyses of different models (models already presented in the EtO Assessment; see, e.g., Appendix D) with different lag periods
    ii. consideration of alternative exposure metrics
    iii. sensitivity analysis from categorical modeling of the lymphoid cancer data with a greater number of categories
b. further characterization of the exposure distributions in the cohort and their changes over time
c. consultation with EPA on working with the cohort study data and review of analyses that can be conducted by EPA staff
d. assistance in responding to SAB comments about the exposure-response modeling:
    i. discuss the extent to which the NIOSH study results are consistent with results from the Union Carbide Cohort study and the Mikoczy et al. (2011) study
    ii. put the extra lifetime risk in terms of the number of lymphoid cancers that are due to exposure to EtO in the cohort

Deliverables (draft and final):
(a) summary of results from exposure-response modeling sensitivity analyses
(b) characterizations of exposure-response distributions and temporal changes
(c) consultations; review of EPA analyses
(d) draft responses and/or edits to EPA draft responses to SAB comments
Due Dates: To be specified in written technical direction after consultation with the contractor

Attachments:
"App D - 15 Aug 2014.pdf" (appendix to EtO assessment)
"steenland.risk.attenuation.june.ehp.2011.pdf"
"steenland2004.pdf"

Task 3: Exposure Characterization for the NIOSH Exposure Assessment

The SAB requested further characterizations of EtO exposure levels estimated from the regression model used in the NIOSH exposure assessment:

a. examination of how exposure levels for different jobs/locations changed over time
b. for time patterns that appear anomalous, some explanation for the changes over time based on parameters in the regression model, i.e., what parameter value changes are responsible for the observed time patterns

The contractor is expected to discuss with EPA the details of how to approach this Task and to reach agreement on the proposed approach. EPA will provide the contractor with an example for item (a) above that was used by an expert consultant at the SAB review meeting (attachment: "exposure levels examples.pdf").

Deliverables (draft and final):
graphical and/or tabular displays for exposure changes over time
written explanations for apparently anomalous time patterns

Due Date: To be specified in written technical direction after consultation with the contractor

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	**Schedule** (all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days after receipt of this PWS
2. Exposure-Response Modeling of NIOSH Cohort Study Data	To be specified in written technical direction
3. Exposure Characterization	To be specified in written technical direction

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the

proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)

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703-347- 8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-49

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Ethylene Oxide - Epidemiology
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A.1,2,4 and B.1,2,5

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/06/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-49

TITLE: Ethylene Oxide - Epidemiology Modeling and Exposure Characterization

---

Principal Section & Paragraph of SOW: A.1,2,4 and B.1,2,5

PERIOD OF PERFORMANCE: date of approval – October 31, 2015

I. PURPOSE

The purpose of the work assignment is to provide services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of a carcinogenicity assessment for Ethylene Oxide. Specifically, this work assignment will provide exposure-response modeling using NIOSH cohort study data, and, separately, characterizations of exposure levels estimated for jobs and locations pertinent to the cohort study.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

These Tasks are undertaken to respond to recommendations of the EPA Science Advisory Board (SAB) after its review (November 18-20, 2014) of the Ethylene Oxide Assessment. All work must be completed before December 31, 2015. This work will begin based on information from the SAB review in November 2014 and the draft written from January 2015. A final review may be available around June or July, 2015. This PWS ends on October 31, 2015, but could be continued into option year 2 if necessary. Undertaking these Tasks will require experience with exposure-response modeling of cohort study data, in particular with two-piece spline models, as well as familiarity with and access to the NIOSH cohort study data and the NIOSH exposure assessment. Further materials related to the Ethylene Oxide Assessment will be provided by EPA.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP
Due Date: 15 days after issuance of this Performance Work Statement (PWS).

Task 2. Exposure-Response Modeling of NIOSH Mortality Cohort Study Data

Exposure-response modeling was conducted for the Ethylene Oxide ("EtO") assessment prior to SAB review. The SAB requested further analyses. These include the following analyses of the mortality cohort study data (other analyses might be required, depending on further communication with SAB):

a. additional exposure-response modeling of the lymphoid cancer mortality data in the NIOSH cohort study, including but not limited to:
   i. sensitivity analyses of different models (specifically, the cumulative exposure Cox regression [log-linear] model, the log cumulative exposure Cox regression model, the tow-piece log-linear spline model, and the two-piece linear spline model [for the linear spline model, ; see, e.g., Appendix D) with different lag periods (0, 5, 10, 15, and 20 years) (generate model fit results and parameter estimates, including the covariances for the two-piece spline models and the profile likelihood 95% upper and lower bound estimates for $\beta 1$ for the two-piece linear spline model).
   ii. sensitivity analyses of the selected two-piece spline model to knot selection (depending on the results of a.i. above, EPA will select a preferred spline model. the sensitivity of this model to knot selection will be examined for a specified range of knots.)
   iii. sensitivity of the selected model to an age × exposure interaction term (generate model fit results with inclusion of the interaction term, including fit statistics particular to the interaction term, to compare with the selected model without that term).
   iv. sensitivity analysis from categorical modeling of the lymphoid cancer data with a greater number of categories (depending on the results of a.i. above, this subtask may not be pursued; if it is conducted, it would involve one categorical analysis with one different number [to be determined] of categories).
b. additional model fit diagnostics for the selected model: please provide the Schoenfeld residuals (observed hazard minus predicted hazard) ("ressch" in SAS) and age at diagnosis for each case and generate a graph of the Schoenfeld residuals plotted against the age of diagnosis. (EPA did not include this information in the draft assessment that the SAB reviewed; this is information that the SAB requested as a result of its review. Please see the example extracted from the Libby amphibole asbestos assessment provided as "*Libby Schoenfeld residuals example.docx*"; however, for EtO, we just need one row for the final selected model.)

c. further characterization of the exposure distributions in the cohort and their changes over time (see Appendix A of this PWS for characteristics of the NIOSH cohort requested by the SAB)
d. further characterization of other characteristics of the cohort (see Appendix A of this PWS for characteristics of the NIOSH cohort requested by the SAB)
e. consultation with EPA on working with the cohort study data and review of analyses that can be conducted by EPA staff
f. assistance in responding to SAB comments about the exposure-response modeling:
    i. discuss the extent to which the NIOSH study results are consistent with results from the Union Carbide Cohort study and the Mikoczy et al. (2011) study
    ii. put the extra lifetime risk in terms of the number of lymphoid cancers that are due to exposure to EtO in the cohort

Deliverables (draft and final):
(a) summary of results from exposure-response modeling sensitivity analyses
(b) characterizations of exposure-response distributions and temporal changes
(c) copies of computer code used for analyses
(d) consultations; review of EPA analyses
(e) draft responses and/or edits to EPA draft responses to SAB comments

Due Dates: To be specified in written technical direction after consultation with the contractor

Materials to be provided separately (by upload to ICF):
"App D - 15 Aug 2014.pdf" (appendix to EtO assessment)
"steenland.risk.attenuation.june.ehp.2011.pdf"
"steenland2004.pdf"
"Steenland2003-epi-breastCA.PDF"
"Libby Schoenfeld residuals example.docx"
"CAAC+EtO+Report+010715.pdf"

Task 3: Assistance to NIOSH for Exposure-Response Modeling of the NIOSH Breast Cancer Incidence Study Data

The SAB also requested further analyses of the breast cancer incidence data; however, these data are not publically available (Dr. Steenland, a former NIOSH investigator, did the analyses of these data for EPA's recent SAB review draft; however, his data-use agreement has expired and is not eligible for renewal). NIOSH might undertake to do some of the requested analyses for EPA. To facilitate NIOSH's conduct of the analyses for EPA, EPA, through this work assignment, might provide assistance to NIOSH, if NIOSH is agreeable. This assistance would most likely take the form of providing NIOSH with consultation and computer code for the analyses, but may involve travel to Cincinnati to work with the NIOSH analyst. See Attachment B of this PWS for the specific analyses that have been requested of NIOSH.

Deliverables (draft and final):
(a) copies of computer code provided to NIOSH for the exposure-response modeling analyses
(b) summary of results from the analyses, including graphical displays (e.g., knot selection, exposure-response models, Schoenfeld residuals)

Due Date: To be specified in written technical direction after consultation with the contractor

Task 4: Exposure Characterization for the NIOSH Exposure Assessment

The SAB requested further characterizations of EtO exposure levels estimated from the regression model used in the NIOSH exposure assessment:

a. examination of how exposure levels for different jobs/locations changed over time
b. for time patterns that appear anomalous, some explanation for the changes over time based on parameters in the regression model, i.e., what parameter value changes are responsible for the observed time patterns

The contractor is expected to discuss with EPA the details of how to approach this Task and to reach agreement on the proposed approach. EPA will provide the contractor with an example for item (a) above that was used by an expert consultant at the SAB review meeting (see "*exposure levels examples.pdf*").

Deliverables (draft and final):

(a) graphical and/or tabular displays for exposure changes over time
(b) written explanations for apparently anomalous time patterns

Due Date: To be specified in written technical direction after consultation with the contractor

Materials to be provided separately (by upload to ICF):

"exposure levels examples.pdf"

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	**Schedule** (all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days after receipt of this PWS
2. Exposure-Response Modeling of NIOSH Cohort Study Data	To be specified in written technical direction
3. Assistance to NIOSH in their exposure-response modeling of the breast cancer incidence data	To be specified in written technical direction
4. Exposure Characterization	To be specified in written technical direction

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Project Officer (PO)

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EPA Work Assignment Manager (WAM)

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Courier Deliveries:
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Technical Advisor (Not a WAM/or COTR)
Jennifer Jinot (Assessment Manager for Ethylene Oxide; EPA Statistican)
703-347-8597 jinot.jennifer@epa.gov

APPENDIX A

Characteristics of the NIOSH Cohort Requested by the SAB

As examples it would be helpful to build the following tables:

- Marginal summaries of workers' ages, exposures, and years of entry to employment
- Cumulative exposure to EtO by duration of employment
- Cumulative exposure to EtO by year of entry to employment
- Cumulative exposure to EtO in each of the risk categories

A useful descriptive summary of the exposure characteristics for cases and controls could include the following:

- Box plot of cumulative total and peak exposures for individual cases and controls
- Time (individual years or 5-year intervals) plot of the distribution of computed Q25, Q50, mean, Q75, Q95 values for annual exposures among the currently working subpopulations of cases and controls
- Summary of % of total case and control individual exposures in the worker histories that are excluded when the EPA- chosen lag of 15 years is imposed

Key characteristics of the NIOSH cases and controls that should be analyzable from the study data set and could be summarized in descriptive tables or figures include the following distributions:

- Gender distribution over time
- Year of entry to the EtO workforce
- Age of entry to the EtO workforce
- Duration of employment in the EtO cohort
- Age and year of departure/retirement from the EtO cohort

APPENDIX B

List of EtO breast cancer incidence analyses requested of NIOSH

The "selected" model refers to the model that EPA selects as the basis for its risk estimates. In the current version of the assessment, the selected model for the breast cancer incidence data is the two-piece linear spline model with cumulative exposure with a 15-year lag and with a knot of 5800 ppm × days. Depending on the results of the sensitivity analyses for lag time (#1), the selected model might change. Some of the analyses listed below will only be needed if the selected model changes, as specified in the list.

The dataset for analysis is the subcohort with interviews, with inclusion of parity and breast cancer in a first-degree relative, for all analyses unless otherwise specified.

It might be useful to refer to Appendix D (the Introduction and Section 1) of the EPA's draft assessment (attached to the conveying email) for a discussion of the modeling that was done and the results of the original analyses that were conducted.

Analyses:

1. sensitivity of the two-piece linear spline model [RR = 1 + ($\beta1 \times exp + \beta2 \times (exp - knot)$), where "exp" is the cumulative exposure taking the lag time into account] to choice of lag time, for lag times of 0 (no lag), 5, 10, 15, and 20 years: generate model fit results and parameter estimates, including the covariances and the profile likelihood 95% upper and lower bound estimates for $\beta1$, for the two-piece linear spline model (see last row of Tables D-1h on page D-20 and D-1i and its footnote "a" on page D-21) with each of the 5 lag times, recalculating the "optimal" knot (i.e., the knot that yields the two-piece spline model with the maximum likelihood) with each lag time (see text on page D-7 regarding knot selection and Figure D-1h on page D-20; please provide a similar figure [or the -2 log likelihoods for each knot tested so that EPA can generate the figure] for the two-piece linear spline model with each of the 5 lag times).

After #1, EPA would need to review the results to determine whether or not to change the selected model. The analyses described in #2 would be needed *only if the selected model changed* after review of the results of #1 (EPA can provide additional clarification at that time, depending on what the selected model is):

2. sensitivity of the two-piece log-linear spline model [log RR = 1 + ($\beta1 \times exp + \beta2 \times (exp - knot)$), where "exp" is the cumulative exposure taking the lag time into account] to choice of lag time, for lag times of 0 (no lag), 5, 10, 15, and 20 years: generate model fit results and parameter estimates, including the covariances, for the two-piece log-linear spline model (see Table D-1c on page D-14) with each of the 5 lag times, recalculating the optimal knot with each lag time (see text on page D-7 regarding knot selection and Figure D-1a on page D-9; please provide a similar figure [or the -2 log likelihoods for each knot tested so that EPA can generate the figure] for the two-piece log-linear spline model with each of the 5 lag times).

After #2, EPA would again need to review the results to determine whether or not to change the selected model. The analyses described in #3, #4, and #5 would be done with *whatever the selected model is* after the review of the results of #1 (and of #2 if applicable) (EPA can provide additional clarification at that time, depending on what the selected model is):

3. sensitivity of selected model to inclusion of potential confounding variables: generate model fit results and parameter estimates for
    a. the selected model with the exclusion of the parity and breast-cancer-in-a-first-degree-relative parameters.
    b. the selected model with the exclusion of the parity parameter.

4. sensitivity of the selected model to an age × exposure interaction term: generate model fit results with inclusion of the interaction term, including fit statistics particular to the interaction term, to compare with the selected model without that term.

5. additional model fit diagnostics for the selected model: please provide the Schoenfeld residuals (observed hazard minus predicted hazard) ("ressch" in SAS) and age at diagnosis for each case so that EPA can generate a graph of the Schoenfeld residuals plotted against the age of diagnosis. (EPA did not include this information in the draft assessment that the SAB reviewed; this is information that the SAB requested as a result of its review. Please see the example extracted from the Libby amphibole asbestos assessment provided among the attachments in the email conveying this memo; however, in our case, we just need one row for the final selected model.)

The analysis described in #6 would be needed *only if the selected model did NOT change* after review of the results of #1:

6. sensitivity of selected two-piece linear spline model to choice of knot: generate model fit results and parameter estimates, including the covariances and the profile likelihood 95% upper and lower bound estimates for β1, as in #1, for the two-piece linear spline model with a 15-year lag time and knots of:
    a. 4800 ppm × days
    b. 6800 ppm × days

The following additional analyses, listed in order of importance, would be needed *only if the selected model changed* after review of the results of #1 (and of #2 if applicable) (EPA can provide additional clarification at that time, depending on what the selected model is):

7. sensitivity of selected model to choice of knot: generate model fit results and parameter estimates, including the covariances and, if the selected model is a linear spline model, the profile likelihood 95% upper and lower bound estimates for β1, for the selected model with knots of:
    a. the optimal knot – 1000 ppm × days
    b. the optimal knot + 1000 ppm × days

8. revised Table D-1a (distribution of cases and mean cumulative exposures in deciles of lagged cumulative exposure; page D-6) using the new lag time.

9. categorical analysis of breast cancer incidence in deciles of lagged cumulative exposure using the new lag time: generate model fit results and parameter estimates as follows:

    a. IF the selected model is log-linear, use log RR categorical model (see Table D-1b on page D-7)
    b. IF the selected model is linear, use log RR categorical model (see Table D-1b on page D-7) AND linear RR categorical model (see Table D-1j on page D-22)

10. IF the selected model is linear, continuous exposure analyses with single-exposure-parameter linear RR models [RR = 1 + β × exp] using the new lag time: generate model fit results and parameter estimates, including the profile likelihood 95% upper and lower bound estimates for β, as follows:
    a. where "exp" is lagged cumulative exposure (see first row of Tables D-1h on page D-20 and D-1i on page D-21)
    b. where "exp" is log lagged cumulative exposure (see second row of Tables D-1h on page D-20 and D-1i on page D-21); note that as stated in Steenland et al. (2004), 1 ppm × day is added to cumulative exposures in lagged analyses to avoid taking the log of 0.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-49

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Ethylene Oxide
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A 1, 2, 4 & B 1, 2, 5

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/06/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$41,756.00	164
Total:	$41,756.00	164

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 04/06/2015	$41,756.00	164
Cumulative Approved:	$41,756.00	164

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-50

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	EPA-Eco-Box
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III.C.

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/28/2015 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-50

TITLE: Technical Support for Development of EPA-Eco-Box (a toolbox for ecological risk assessors)

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2015.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for the development of EPA-Eco-Box (a toolbox for ecological risk assessors).

II. BACKGROUND AND OBJECTIVES.

EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) developed and released EPA-Expo-Box in 2013. EPA-Expo-Box is a toolbox for exposure assessors and includes links to more than 800 resources used in human exposure assessments. EPA/NCEA is now developing EPA-Eco-Box as a web-based compendium of tools used in ecological risk assessment. It will be comprised of a series of Tool Sets, each containing modules that address topics in ecological risk assessment. Each toolbox module will contain a description of the topic and links to ecological risk assessment resources that address that topic, including databases, models, guidance documents, and other relevant tools. A search interface will allow users to identify resources using keywords or topics. Technical assistance will be required for developing the overall structure of EPA-Eco-Box, including: identifying key topic areas and modules, developing Tool Set module content, populating the Master Tool List, and identifying other relevant links. Development of the website to house EPA-Eco-Box is not included in this work assignment.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of five tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall develop an outline of the structure of EPA-Eco-Box.

EPA-Expo-Box was designed as six Tool Sets, each containing a series of modules that address topics in human exposure assessment. A similar structure is being considered for EPA-Eco-Box. The contractor shall assist EPA designing the structure of EPA-Eco-Box by developing a draft outline that includes both the proposed Tool Sets and the proposed modules to be included in each of the tool sets. It is anticipated that EPA-Eco-Box will include no more than six Tools Sets. The contractor shall consult EPA's *Guidelines for Ecological Risk Assessment* (US EPA, 1998) and other relevant guidance documents to ensure that the proposed structure is consistent with standard ecological risk assessment practices. **Within 3 weeks of receiving work plan approval,** the contractor shall submit and a draft outline of the structure of EPA-Eco-Box, and arrange for a conference call with the EPA-COR to discuss the content of the outline. **Within 2 weeks after receiving COR comments on the outline**, the contractor shall revise and finalize the outline. The contractor shall not develop the contents of the Tool Sets or modules until the final outline for the structure of EPA-Eco-Box is approved by the COR.

Deliverable 2a: The contractor shall submit a draft outline of the Tool Sets and modules, and arrange a conference call with the COR **within 3 week after the receiving work plan approval**.

Deliverable 2b: The contractor shall finalize the outline **within 2 weeks of receiving comments from the COR.**

Task 3. The contractor shall assist in developing the content for EPA-Eco-Box Tool Sets and modules.

The contractor shall prepare draft content for EPA-Eco-Box. This shall include brief introductory text for each of the Tool Sets, as well as text and tool lists for each of the modules. Module content may also include graphics, photo images, or other types of reference materials, as needed to convey concepts of ecological risk assessment, as described in relevant EPA guidance documents. The COR will designate, via technical direction, the order of the Tool Sets for which the contractor shall develop content. The draft content for the each of the assigned Tool Sets shall be submitted to the COR **within 4 weeks of receiving technical direction from the COR.** The contractor shall submit final content **within 2 weeks of receiving comments on the draft content from the COR.**

Deliverable 3a: The contractor shall submit draft Tool Set and module content **within 4 weeks after being notified by the COR that they should begin work on.**

Deliverable 3b: The contractor shall submit final Tool Set and module content **within 2 weeks of receiving comments on the draft content from the COR.**

Task 4. The contractor shall develop a Master Tool List for EPA-Eco-Box.

A Master Tool List for EPA-Expo-Box was developed under work assignment 1-13 of this contract to provide a comprehensive listing of all the tools included in the toolbox, and is used to:

(1) populate tables within each of the Tool Set modules with tools relevant to that topic area; and
(2) allow the toolbox to be searched using key words.

A Master Tool List will also be needed for EPA-Eco-Box and will serve these same purposes. The contractor shall develop a Master Tool list for EPA-Eco-Box that will provide a listing of all tools to be included in EPA-Eco-Box along with a brief description, URL, and relevant key words. The contractor shall submit a draft of the basic structure of the Master Tool List to the COR **within 2 weeks of finalizing the outline of the structure of EPA-Eco-Box**. **Within 2 weeks after completing any necessary revisions**, based on the COR's comments, the contractor shall develop the final structure of the Master Tool List and submit it to the COR. The contractor shall populate the Master Tool List with the tool lists developed for each of the Tool Sets modules and deliver the final Master Tool List to the COR **within 6 weeks of finalizing the content for the last of the Tool Sets and modules** assigned by the COR.

Deliverable 4a: The contractor shall submit a draft of the basic structure of the Master Tool List to the COR **within 2 weeks after finalizing the outline of EPA-Eco-Box.**

Deliverable 4b: The contractor shall submit the final structure of the Master Tool List **within 2 weeks after receiving comments from the COR.**

Deliverable 4c: The contractor shall submit the final Master Tool List to the COR, **within 6 weeks of finalizing the content for the last of the Tool Set modules assigned by the COR.**

Task 5. The contractor shall assist in identifying additional over-arching topics to be included in EPA-Eco-Box as Quick Links

EPA-Expo-Box includes links several over-arching topic areas that are relevant to human exposure assessment. The contractor shall identify and propose a minimum of 6 over-arching topics that are relevant to ecological risk assessment to be included as Quick Links in EPA-Eco-Box. Such links may include those relevant to data quality, key EPA guidance, or other important topics. The contractor shall provide the COR with a list of proposed Quick Link topics **within 4 weeks of finalizing the outline of the structure of EPA-Eco-Box.**

Deliverable 5a: The contractor shall provide the COR with a list of proposed Quick Links **within 4 weeks of finalizing the outline of the structure of EPA-Eco-Box.**

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a	Establish communication via conference call	Within 1 week after receipt of work assignment

2a	Submit draft outline of Tool Sets and modules	Within 3 weeks of receiving work plan approval
2b	Submit final outline of Tool Sets and modules, and arrange conference call with EPA COR	Within 2 weeks of receiving comments on outline from EPA COR
3a	Submit draft Tool Set content	Within 4 weeks of being assigned by COR
3b	Submit final Tool Set content	Within 2 weeks of receiving comments on outline from EPA COR
4a	Master Tool List draft structure	Within 2 weeks of finalizing outline of EPA-Eco-Box
4b	Master Tool List final structure	Within 2 weeks of COR comments
4c	Final Master Tool List	Within 6 weeks of finalizing content
5a	Propose Quick Links	Within 4 weeks of finalizing outline of EPA-Eco-Box

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager	**Alternate WAM**
Linda Phillips US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-0366 FAX #: (703) 347-8690 Email: phillips.linda@epa.gov	Jacqueline Moya US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-8539 FAX #: (703) 347-8694 Email: moya.jacqueline@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-50

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	EPA-Eco-Box
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III.C.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/28/2015 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$82,786.00	998
Total:	$82,786.00	998

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 02/18/2015	$82,786.00	998
Cumulative Approved:	$82,786.00	998

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107